Patent Application
Attorney Docket No.: 64118.000044

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of: | : | |
| | : | |
| Vincent Bryan *et al.* | : | Group Art Unit: 1173 |
| | : | |
| Appln. No.: 08/944,234 | : | |
| | : | Examiner: Lien M. Ngo |
| Filed: Ocotber 6, 1997 | : | |
| | : | |
| For: DRILL HEAD FOR USE IN PLACING AN INTERVERTEBRAL DISC DEVICE | : | |

**Mail Stop: Appeal Brief--Patents**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37**

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## APPEAL BRIEF

In response to the Office Action dated March 31, 2005, finally rejecting pending claims 1-3, 5-7, 13-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97, 100-102, 104-109, 111, 114-125, 128 and 130-138, Appellants respectfully request that the Board of Patent Appeals and Interferences reconsider and withdraw the rejections of record, and allow the pending claims, which are attached hereto as an Appendix A.

## I. REAL PARTY IN INTEREST

The real party in interest is Medtronic Sofamor Danek, the assignee of the above-referenced application.

## II. RELATED APPEALS AND INTERFERENCES

There are no known related appeals or interferences.

## III. STATUS OF CLAIMS

Claims 1-3, 5-7, 13-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97,

100-102, 104-109, 111, 114-138 are pending in this application. The rejection of claims 1-3, 5-7, 13-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97, 100-102, 104-109, 111, 114-125, 128 and 130-138 is appealed.

## IV. STATUS OF AMENDMENTS

No amendments to the claims have been filed subsequent to the final rejection dated March 31, 2005.

## V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Appellants believe that a brief discussion of the background technology, followed by a brief summary of the embodiments of the invention and the problems solved by the embodiments of the present invention, will assist the Board of Patent Appeals and Interferences (hereinafter referred to as "the Board") in appreciating the significant advances made by the embodiments of the present invention. Finally, concise explanations of each of the independent claims are provided, including reference to exemplary portions of the specification and figures.

### A. The Background

This invention relates generally to drill heads and more particularly to drill heads for use in placing an intervertebral disc device.

The herniation of a spinal disc and the often resultant symptoms of intractable pain, weakness, sensory loss, incontinence and progressive arthritis are among the most common of debilitating processes affecting mankind. If a patient's condition does not improve after conservative treatment, and if clear physical evidence of nerve root or spinal cord compression is apparent, and if correlating radiographic studies (i.e., MRI or CT imaging or myelography) confirm the condition, surgical removal of the herniated disc may be indicated. The process of discectomy--as the name implies--involves the simple removal of the disc without attempt to

replace or repair the malfunctioning unit. In the United States in 1985, over 250,000 such operations were performed in the lumbar spine and in the cervical spine.

Statistics suggest that present surgical techniques are likely to result in short-term relief, but will not prevent the progressive deterioration of the patient's condition in the long run. Through better pre-operative procedures and diagnostic studies, long-term patient results have improved somewhat. But it has become clear that unless the removed disc is replaced or the spine is otherwise properly supported, further degeneration of the patient's condition will almost certainly occur.

In the mid-1950's and 60's, Cloward and Smith & Robinson popularized anterior surgical approaches to the cervical spine for the treatment of cervical degenerative disc disease and related disorders of the vertebrae, spinal cord and nerve root; these surgeries involved disc removal followed by interbody fusion with a bone graft. It was noted by Robinson (Robinson, R. A.: The Results of Anterior Interbody Fusion of the Cervical Spine, J. Bone Joint Surg., 440A: 1569-1586, 1962) that after surgical fusion, osteophyte (bone spur) reabsorption at the fused segment might take place. However, it has become increasingly apparent that unfused vertebral segments at the levels above and below the fused segment degenerate at accelerated rates as a direct result of this fusion. This has led some surgeons to perform discectomy alone, without fusion, by a posterior approach in the neck of some patients. However, as has occurred in surgeries involving the lower back where discectomy without fusion is more common as the initial treatment for disc herniation syndromes, progressive degeneration at the level of disc excision is the rule rather than the exception. Premature degenerative disc disease at the level above and below the excised disc can and does occur.

Spine surgery occasionally involves fusion of the spine segments. In addition to the

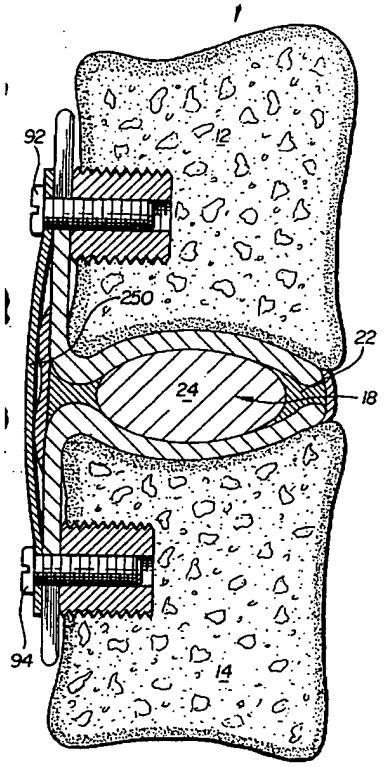
problems created by disc herniation, traumatic, malignant, infectious and degenerative syndromes of the spine can be treated by fusion. Other procedures can include bone grafts and heavy duty metallic rods, hooks, plates and screws being appended to the patient's anatomy; often they are rigidly and internally fixed. None provide for a patient's return to near-normal functioning. Though these procedures may solve a short-term problem, they can cause other, longer term, problems.

A number of attempts have been made to solve some of the problems described above by providing a patient with spinal disc prostheses, or artificial discs of one sort or another. For example, Steffee, U.S. Pat. No. 5,031,437, describes a spinal disc prosthesis having upper and lower rigid flat plates and a flat elastomeric core sandwiched between the plates. Frey et al., U.S. Pat. Nos. 4,917,704 and 4,955,908, disclose intervertebral prostheses, but the prostheses are described as solid bodies.

U.S. Pat. Nos. 4,911,718 and 5,171,281 disclose resilient disc spacers, but no inter-connective or containing planes or like elements are suggested, and sealing the entire unit is not taught.

Co-pending, related U.S. patent application Ser. No. 08/681,230 [now U.S. Patent No. 5,674,296] incorporated herein by reference, provides a vertebral disc endoprosthesis which addresses these shortcomings of the prior art. The endoprosthesis comprises a resilient body formed of a material varying in stiffness from a relatively stiff exterior portion to a relatively supple central portion. A concaval-convex means at least partly surrounds that resilient body so as to retain the resilient body between adjacent vertebral bodies of a patient's spine. If medical considerations so indicate, several disc endoprosthesis can be combined with one or more endoprosthetic vertebral bodies in an entire assembly.

Such an endoprothesis, for example, can be depicted as follows:




In the above figure, the endoprosthesis 24 is provided between two adjacent intervertebral bodies.

In order to place the above endoprosthesis in a patient's spine, the bone of the two opposing intervertebral bodies must be prepared in such a manner so as to accept the concaval-convex shape of endoprosthesis. However, currently available drill heads are not always capable of being fit into the narrow space between two opposing intervertebral bodies. Further, the narrow space between two opposing intervertebral bodies cannot always be expanded to allow admittance of currently available drill heads.

Thus, it is an object of the instant invention to provide a drill head which can fit within the narrow space between two opposing intervertebral bodies.

It is another object of the instant invention to provide a drill head which can prepare the

bone of the two opposing intervertebral bodies to accept the concaval-convex shape of an endoprosthesis.

This object is achieved, in a preferred embodiment, by employing a drill head as depicted below. The drill is provided with a form cutter 29 which rotates about a shaft and which mills a concave shape into the intervertebral surface corresponding to the shape of a prosthetic to be implanted. Mechanically, the drill head is such that the form cutter can enter the intervertebral space between two adjacent vertebrae and can enter such space in a direction parallel to the vertebrae such that it can cut in a direction angled away from tool entry.

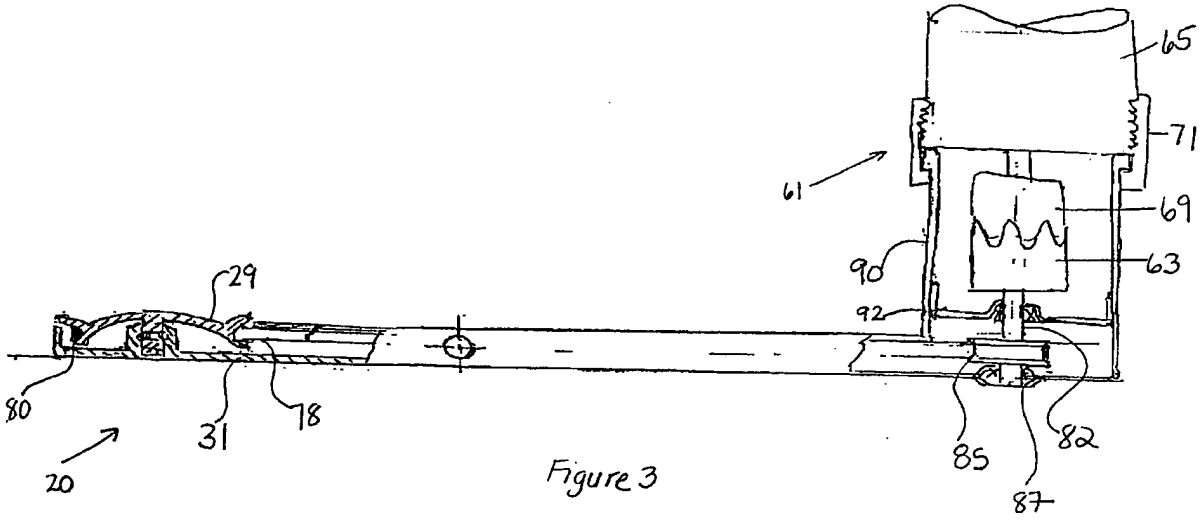



Figure 3

### B. The Embodiments of The Present Invention

The instant invention overcomes the deficiencies of the prior art devices by providing a drill or milling head with a narrow profile which can fit in the space between two opposing intervertebral bodies. Moreover, the device can handle torque and power in sufficient amounts as to be capable of milling on a surface and acting in a direction angled away from the direction of device entry into the space between those intervertebral bodies.

The drill head of the instant invention is provided with a form cutter having a convex shape so as to prepare the bone of vertebral bodies to accept the concaval-convex shape of an endoprosthesis. In addition, the cutter may have the ability to cut in the direction of tool entry into the space. *See* ¶'s 0013 and 0014 of the Original Published Application.

### C. Explanation of Independent Claim 1[1]

1. A drill head (20) for preparing the bone of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis comprising (¶19):

a form cutter (29) having a profile capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined endoprosthesis surface shape (¶20);

drive means (¶24; Fig. 2:24) for providing a driving force to the form cutter (¶24), and

means for housing (¶20: Fig. 2:31) the form cutter and the drive means (¶24; Fig. 2:24),

wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies (¶13).

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[1] The terms of the pending application claims are referenced to the disclosure of the original specification. Appellants respectfully submit that additional support is found in the substitute specification filed on December 4, 2002.

**D. Explanation of Independent Claim 15**

15. A drill head for preparing the bone of two opposing vertebral bodies to accept the concaval-convex shape of an endoprosthesis comprising (¶20):

a form cutter (29) having a support shaft (51) capable of imparting a concave shape to the bone of vertebral bodies (¶¶20 and 22);

drive means (¶24; Fig. 2:24) for providing a driving force to the form cutter, the drive means including a drive shaft (¶24); and

means for housing (¶20; Fig 2:31) the form cutter and the drive means (¶27),

wherein the angle between the support shaft of the form cutter and the drive shaft is approximately 96° (¶26).

**E. Explanation of Independent Claim 18**

18. A milling apparatus for preparing surfaces of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis comprising (¶20):

a rotary form cutter having a profile matching the predetermined shape of the endoprosthesis, the rotary form cutter rotatable about a rotation axis (¶19);

a drive having proximal and distal ends, the drive operatively coupled to the rotary form cutter at the distal end to provide a force for rotating the rotary form cutter (¶24); and

an elongate housing containing the rotary form cutter and the drive, the elongate housing having a longitudinal axis in the elongate direction (¶ 20);

wherein the rotary form cutter cuts an imparted shape into the surfaces of the vertebral bodies that matches the predetermined shape of the endoprosthesis by rotation of the rotary form cutter (¶14).

**F. Explanation of Independent Claim 25**

25. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising (page 4, lines 1-3):

an elongated shaft portion (Fig 2: 40);

a housing disposed at the distal end of said elongated shaft portion (Figs. 1, 2: 31);

a drive means (¶24; Fig. 2:24);

a drive source operably connected to said drive means (Fig. 2:61); and

a form cutter mountable on said housing and movable by said drive means, wherein (Fig. 2: 29; page 6, lines 11-13):

said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means (¶20).

**G. Explanation of Independent Claim 41**

41. A form cutter for preparing a space between adjacent vertebral bodies to receive an insert, said form cutter having (¶¶10 and 11):

at least one milling surface and being mountable on a device capable of moving said form cutter to cause said at least one milling surface to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies (¶¶ 19 and 20),

said at least one milling surface having a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis shape of the insert to be received between the adjacent vertebral bodies (¶19).

**H. Explanation of Independent Claim 47**

47. A device for preparing a space in a human spine across a disc space and into the end plates of adjacent vertebral bodies to receive an interbody spinal insert, said device comprising (¶¶13 and 14):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive means (¶24; Fig. 2:24);

a drive source for powering said drive means (¶24);

a form cutter mountable on said housing (¶22); and

a coupling means for connecting and imparting motion from said drive means to said form cutter (¶25),

wherein:

said form cutter has at least one milling surface selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies as said form cutter is moved by said drive means (¶20); and

said milling surface is configured to have a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of the interbody spinal insert (¶20).

**I. Explanation of Independent Claim 49**

49. A device for preparing a space to receive an interbody insert within and between the adjacent surfaces of vertebral bodies disposed adjacent a disc space, said device comprising (¶¶13 and 14):

an elongated shaft containing at least a portion of a drive means (¶24; Fig. 2:24);

a housing positioned at the distal end of said elongated shaft portion (¶27); and

a form cutter disposed on said housing and operably connected to said drive means to be driven thereby (¶24),

wherein:

said form cutter has a milling surface (¶20);

said milling surface has a profile that imparts a shape to the bone of the vertebral bodies which mates with the predetermined endoprosthesis surface shape of the insert to be implanted (¶20);

said milling surface has a configuration adapted to remove bone from the vertebral bodies to prepare the vertebral bodies to receive the insert (¶20); and

said milling surface of said form cutter is configured to be generally parallel to a receiving surface that is formed on one of the vertebral bodies by said device (¶¶13 and 14).

**J. Explanation of Independent Claim 67**

67. A device for preparing a space in the human spine to receive an insert between adjacent vertebral bodies, said device comprising (¶¶13 and 14):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive means (¶24; Fig. 2:24);

a drive source operably connected to said drive means (¶25);

a form cutter mountable on said housing and movable by said drive means (¶24);

said form cutter having at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means (¶20);

said drive means including a drive shaft disposed within said elongated shaft portion (¶24);

said drive shaft being rotatably driven by said drive means (¶24); and

said drive shaft being operably coupled to said form cutter (¶24).

**K. Explanation of Independent Claim 82**

82. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising (¶¶13 and 14):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive means (¶24; Fig. 2:24);

a drive source operably connected to said drive means (¶25);

a form cutter mountable on said housing and movable by said drive means (¶24), wherein:

said form cutter has at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means (¶20); and

said housing has a surface formed on a side of said housing opposite said milling surface (Fig. 2).

**L. Explanation of Independent Claim 97**

97. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising (¶¶13 and 14):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive means (¶24; Fig. 2:24);

a drive source operably connected to said drive means (¶25); and

a form cutter mountable on said housing and movable by said drive means (¶24), wherein:

said form cutter has at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means (¶20).

**M. Explanation of Independent Claim 114**

114. A form cutter for preparing a space between adjacent vertebral bodies to receive an insert, said form cutter having (¶¶ 10 and 11):

at least one milling surface and being mountable on a device capable of moving said form cutter to cause said at least one milling surface to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies (¶¶19 and 20);

said at least one milling surface having a profile that imparts a shape to the bone on the vertebral bodies which mates with a predetermined endoprosthesis surface shape of the insert to be received between the adjacent vertebral bodies (¶20);

said at least one milling surface having a perimeter that is at least in part arcuate (Figs. 1 and 2, 29); and

said form cutter having a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine (Fig. 2, 44).

**N. Explanation of Independent Claim 120**

120. A device for preparing a space in a human spine across a disc space and into the end plates of adjacent vertebral bodies to receive an interbody spinal insert, comprising (¶¶13 and 14):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive means (¶24; Fig. 2:24);

a drive source operably connected to said drive means (¶25);

a form cutter mountable on said housing and movable by said drive means (¶24);

drive means that operatively couples said form cutter to said drive source to move said form cutter (¶24);

said form cutter having a milling surface selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies as said form cutter is moved by said drive means in a plane generally parallel to the predetermined surface contour to be formed in said vertebral body (¶¶14, 18 and 20) and ;

said form cutter being driven in rotary motion by said drive means (¶24); and

said milling surface being configured to have a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of said interbody spinal insert (¶20).

**O. Explanation of Independent Claim 121**

121. A form cutter for preparing a space between adjacent vertebral bodies to receive an insert, said form cutter having (¶¶10 and 11):

at least one top milling surface for removing bone (Fig. 2; 42, 44);

a bottom surface opposite said at least one top milling surface adapted to mount on a device capable of moving said form cutter (Fig. 2; 29, 47);

said at least one top milling surface of said moving form cutter being capable of removing bone from an end plate of at least one of said adjacent vertebral bodies to create at least one surface in said end plate having a predetermined contour (¶20);

said at least one top milling surface having a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of said insert to be received between said adjacent vertebral bodies (¶20); and

said form cutter having a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine (Fig. 2; 44).

**P. Explanation of Independent Claim 126**

126. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising (¶¶13 and 14):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive means (¶24; Fig. 2:24);

a drive source operably connected to said drive means (¶25); and

a form cutter mountable on said housing and movable by said drive means (¶24), wherein:

said form cutter has at least one milling surface selected to create a concaval-convex surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means, said form cutter having a beveled gearing surface on the undersurface of the form cutter, wherein said beveled gearing surface cooperates with a pinion gear provided on the distal end of

a drive shaft (¶20).

**Q. Explanation of Independent Claim 127**

127. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising (¶¶13 and 14):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive shaft (¶24);

a drive source operably connected to said drive shaft (¶25); and

a form cutter mountable on said housing and movable by said drive shaft (¶24), wherein:

said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive shaft, and an undersurface having a beveled gearing surface which cooperates with a pinion gear on said drive shaft (¶20).

**R. Explanation of Independent Claim 128**

128. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising (¶¶13 and 14):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive means (¶24; Fig. 2:24);

a drive source operably connected to said drive means (¶25); and

a form cutter mountable on said housing and movable by said drive means (¶24), wherein:

said form cutter has at least one milling surface selected to create a concaval-convex

surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means (¶¶20 and 24).

**S. Explanation of Independent Claim 129**

129. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising (¶¶13 and 14):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive shaft (¶24);

a drive source operably connected to said drive shaft (¶25); and

a form cutter mountable on said housing and movable by said drive shaft, wherein: said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive shaft, and an undersurface having a tooth surface which cooperates with a pinion gear on said drive shaft (¶¶20 and 24).

**T. Explanation of Independent Claim 130**

130. A device for preparing the bone of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis comprising (¶20):

a single form cutter having a profile capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined endoprosthesis surface shape (¶19);

drive means (¶24; Fig. 2:24) for providing a driving force to the form cutter (¶24), and

means for housing (¶20; Fig. 2:31) the form cutter and the drive means (¶20),

wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies and the head can perform milling action in a

direction angled away from the direction of head entry into a space between opposed bodies (¶13 and original claim 1)

**U. Explanation of Independent Claim 131**

131. A device for preparing the bone of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis comprising (¶20):

a form cutter having a convex shape so as to prepare the bone of vertebral bodies to accept the concaval-convex shape of an endoprosthesis (¶20);

drive means (¶24; Fig. 2:24) for providing a driving force to the form cutter (¶24), and

means for housing the form cutter and the drive means (¶¶27),

wherein the form cutter has a profile having a height such that it is capable of being admitted into the space between two opposing vertebral bodies, and a head that can perform milling action in a direction angled away from the direction of head entry into a space between opposed bodies (¶13 and original Claim 1).

**V. Explanation of Independent Claim 132**

132. A device for preparing a space in a human spine to receive an endoprosthesis device between adjacent vertebral bodies, said device comprising (¶20):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive means (¶24; Fig. 2:24);

a drive source operably connected to said drive means (¶25); and

a form cutter mountable on said housing and movable by said drive means (¶24), wherein:

said form cutter has a profile selected to impart a shape in the bone of the vertebral bodies that mates with the endoprosthesis device as said form cutter is moved by said drive means (¶¶20 and 24).

**W. Explanation of Independent Claim 133**

133. A device for preparing a space in a human spine to receive an endoprosthesis device between adjacent vertebral bodies, said device comprising (¶20):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive means (¶24);

a drive source operably connected to said drive means (¶25); and

a form cutter mountable on said housing and movable by said drive means (¶24); and

means for preparing a space in a human spine (¶20; Fig. 2:20) to receive the endoprosthesis device between adjacent vertebral bodies, said space comprising a surface contour in at least one of the adjacent vertebral bodies (¶22).

**X. Explanation of Independent Claim 134**

134. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising (¶20):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive means (¶24; Fig. 2:24);

a drive source operably connected to said drive means (¶25); and

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has at least one vertebral body surface contour milling surface selected to

create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means (¶20).

**Y. Explanation of Independent Claim 135**

135. A device for preparing the bone of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis comprising (¶20):

a form cutter having a profile capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined endoprosthesis surface shape (¶20);

drive means (¶24; Fig. 2:24) for providing a driving force to the form cutter (¶24), and

means for housing the form cutter and the drive means (¶27),

wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies and the head can perform milling action in a direction angled away from the direction of head entry into a space between opposed bodies and rotate about a shaft extending perpendicularly from its undersurface and the space between said opposing vertebral bodies (¶¶20 and 22 and original Claim 1).

**Z. Explanation of Independent Claim 136**

136. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising (¶20):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive means (¶24; Fig. 2:24);

a drive source operably connected to said drive means (¶25); and

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means, said milling surface positioned to mill in a direction perpendicular to said elongated shaft portion (¶¶20 and 22).

**AA. Explanation of Independent Claim 137**

137. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising (¶20):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive means (¶24; Fig. 2:24);

a drive source operably connected to said drive means (¶25); and

a form cutter mountable on said housing and movable by said drive means, wherein: said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means, said surface contour being generally parallel to said elongated shaft portion (¶20; Fig. 2) .

**BB. Explanation of Independent Claim 138**

138. A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising (¶20):

an elongated shaft portion (¶24);

a housing disposed at the distal end of said elongated shaft portion (¶27);

a drive means (¶24; Fig. 2:24);

a drive source operably connected to said drive means (¶25); and

a form cutter mountable on said housing and movable by said drive means (¶¶ 22 and 24), wherein:

said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means, said at least one milling surface being entirely within an area formed by the adjacent vertebral bodies during milling (¶¶19 and 23).

## VI. ISSUES

The issues on appeal are whether the following rejections are proper: (1) the objection under 35 U.S.C. §132 to paragraph 52 of the substitute specification introduced by amendment on December 4, 2002 as allegedly introducing new matter, (2) the rejection under 35 U.S.C. §112, 1st paragraph, of claims 131, 134 and 137 (3) under 35 U.S.C. § 102(e) of Claims 1-20, 23 and 24 Based on U.S. Patent No. 4,197,645 to Scheicher ("Scheicher").

## VII. ARGUMENT

### A. The Objection Under 35 U.S.C. §132 to Paragraph 52 of the Substitute Specification Introduced by Amendment on December 4, 2002, as Allegedly Introducing New Matter is Improper

On page 2 of the Office Action, the amendment filed on December 4, 2002, is objected to under 35 U.S.C. §132 because it allegedly introduces new matter into the disclosure. This rejection is respectfully traversed.

As stated in MPEP §2163.07(b), information incorporated by reference into an application is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Further, as stated in MPEP § 2163.07, mere rephrasing of a passage does not constitute new matter. Accordingly, a rewording of a passage where the same meaning remains intact is permissible. *In re Anderson*, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973).

Regarding paragraph 52 of the substitute specification, the Office Action alleges that the

original disclosure does not support the method of milling a vertebral body using the present invention drill head "with a form cutter having at least one milling surface selected (sic) a predetermined surface contour in one of the adjacent vertebral bodies as the form cutter is moved by drive means 24." The Office is requiring that Appellants cancel the allegedly new matter.

On December 2, 2002, Appellants submitted a substitute specification that adds matter disclosed in co-pending U.S. Patent Application Serial No. 08/681,230 [now U.S. Patent No. 5,674,296] (the "'296 patent"), which the original specification expressly incorporated by reference. (*See, e.g.,* Page 3, lines 7-8). Accordingly, the substitute specification does not introduce new matter.

Paragraph 52 of the substitute specification presently provides as follows:

> After the holes have been formed and the anchors 202, 204 implanted, a bone surface milling jig (not shown) is affixed to the anchors 202, 204 and the desired surfaces of the predetermined shape are formed on the inferior and superior surfaces of the opposing vertebral bodies using a drill head. The desired surface of predetermined shape 212, 214 is formed by contacting the inferior or superior surface of opposing vertebral bodies 112, 114, ***with a form cutter having at least one milling surface 42, 44 selected to create a predetermined surface contour in one of the adjacent vertebral bodies as the form cutter is moved by drive means 24***, using one of a selection of predetermined form cutter sizes.[2]

*See* Paragraph 52, Substitute Specification (emphasis added).

Appellants respectfully submit that paragraph 52 is not new matter, but is indeed fully supported by the disclosures of the original specification and the '296 patent. In particular, Appellants respectfully submit that Paragraph 52 is a composite of the disclosures of the original specification and the '296 patent, which was expressly incorporated by reference into the above application. More specifically, paragraph 52 of the substitute specification is supported by Col.

[2] Emphasized portion indicates portion of the paragraph 52 that the Office claims comprises new matter.

6, lines 56-62 of the '296 patent, and by page 5, lines 5-18 of the original specification.

Col. 6, lines 56-62 of the '296 patent provides as follows:

> After the holes have been formed and the anchors 102, 104 implanted, a bone surface milling jig (not shown) is affixed to the anchors 102, 104 and the desired concave surfaces of predetermined shape are formed on the inferior and superior surfaces of the opposing vertebral bodies using one of a selection of predetermined milling head or bit sizes.

Page 5, lines 5-16 of the original specification provides as follows:

> As seen in FIG. 2, the drill head 20 includes a form cutter 29 carried by a housing 31 having an upstanding wall 35 and a shaft support 37 for supporting the form cutter 29. The housing 31 further includes an elongated shaft portion 40 which houses the drive shaft discussed below. ***To provide a drill head which can prepare the bone of the two opposing intervertebral bodies to accept the concaval-convex shape of an endoprosthesis, the illustrated form cutter 29 has a convex milling surface 42. This convex surface 42 of the form cutter 29 functions to provide the bone of a vertebral body with a mating shape complementary to the concaval-convex shape of the endoprosthesis which is the subject of co-pending U.S. patent application Ser. No. 08/681,230 [now the '296 patent]***. As illustrated, this tool drill or milling head can mill in a direction angled away from the direction of device entry into the space between the intervertebral bodies. That edge 44 provides the cutter 29 with the ability to cut in the direction of tool entry into the space between two opposed vertebral bodies.

(emphasis added).

Further, Figure 2 discloses a rotary form cutter 29 that has two distinct milling surfaces, an inner convex milling surface 42, surrounded by an outer concaval milling surface which terminates at peripheral edge 44 (Specification, ¶¶25-26), and thus shows a form cutter having at least one milling surface 42, 44 as stated in Paragraph 52.

In view of the above, Appellants respectfully submit that paragraph 52 of the substitute specification is fully supported by the original specification. Accordingly, Appellants respectfully request that objection to paragraph 52 of the substitute specification be withdrawn.

**B. The Rejection Under 35 U.S.C. §112, 1st Paragraph, of Claims 131, 134 and 137**

On pages 2-3 of the Office Action, claims 131, 134 and 137 were rejected under 35 U.S.C. §112, 1st paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Appellants respectfully traverse this rejection because the claims have full support in the specification as originally filed.

As stated in MPEP § 2163.02, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed. The subject matter of the claim need not be described literally (i.e., using the same terms or in *haec verba*) in order for the disclosure to satisfy the description requirement.

1. Claim 131

Regarding claim 131, the Office asserts that it cannot be understood why a form cutter having a convex shape can prepare the bone to accept a concaval-convex shape of an endoprosthesis.

At the outset, Appellants respectfully submit that this is not a proper rejection under 35 U.S.C. §112, first paragraph. Merely professing confusion on why a form cutter having a convex shape can prepare the bone to accept a concaval-convex shape of an endoprosthesis does not comprise a proper rejection under 35 U.S.C. §112, for paragraph. This deficiency aside, Appellants have construed the rejection as alleging the specification's failure to describe the limitation "a form cutter having a convex shape so as to prepare the bone of vertebral bodies to accept the concaval-convex shape of an endoprosthesis" in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Appellants traverse this rejection and respectfully submit that the original specification does properly describe the alleged missing matter. For example, page 5, lines 10-13 of the original specification expressly states that the "convex shape of the form cutter functions to provide the bone of a vertebral body with a mating shape complementary to the concaval-convex shape of the endoprosthesis which is the subject of the [the '296 patent]."

In view of the above, Appellants respectfully request that pending rejection of claim 131 under 35 U.S.C. §112, first paragraph be withdrawn.

2. Claim 134

Regarding claim 134, the Office alleges that "said form cutter has at least one vertebral body surface contour milling surface" is not supported in the specification.

Appellants traverse this rejection and respectfully submit that the original specification properly discloses that "said form cutter has at least one vertebral body surface contour milling surface." For example, page 5, lines 10-16 provides:

> This convex shape of the form cutter functions to provide the bone of a vertebral body with a mating shape complementary to the concaval-convex shape of the endoprosthesis which is the subject of the [the '296 patent]. As illustrated, this tool drill or milling head can mill in a direction angled away from the direction of device entry into the space between the intervertebral bodies. That edge 44 provides the cutter 29 with the ability to cut in the direction of tool entry into the space between two opposed vertebral bodies.

Further, Figure 2 discloses a rotary form cutter 29 that has two distinct milling surfaces, an inner convex milling surface 42, surrounded by an outer concaval milling surface which terminates at peripheral edge 44 (Specification, ¶¶25-26), and thus shows a form cutter having at least one milling surface 42, 44 as stated in Paragraph 52.

Appellants respectfully submit that the original specification -- as evidenced by the above excerpt and Figure 2 -- clearly conveys to those skilled in the art at the time the application was

filed the claim limitation that "said form cutter has at least one vertebral body surface contour milling surface."

In view of the above, Appellants respectfully request that pending rejection of claim 134 under 35 U.S.C. §112, first paragraph be withdrawn.

3. Claim 137

Regarding claim 137, the Office alleges that "said surface contour being generally parallel to said elongated shaft portion" is not supported in the specification.
Appellants traverse this rejection and respectfully submit that the original specification properly discloses that "said surface contour being generally parallel to said elongated shaft portion." For example, Figure 2 discloses a rotary form cutter 29 that one of ordinary skill in the art would appreciate is generally parallel to the elongated shaft portion.40. In particular, Appellants respectfully submit that one of ordinary skill in the art would appreciate that the top-most point of form cutter 29 has a tangential line that is generally parallel to the elongated shaft portion 40.

Appellants respectfully submit that the original specification -- as evidenced by the disclosure of Figure 2 -- clearly conveys to those skilled in the art at the time the application was filed the claim limitation that "said surface contour being generally parallel to said elongated shaft portion." In view of the above, Appellants respectfully request that pending rejection of claim 137 under 35 U.S.C. §112, first paragraph be withdrawn.

### C. The Rejection Under 35 U.S.C. § 112, 2nd Paragraph of Claims 130, 133 AND 135

On page 3 of the Office Action, Claims 130, 133 and 135 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Appellant is presently precluded from amending the claims to cure this deficiency, but will promptly do so once a

resolution of the issues raised in this appeal are resolved. With regards to claims 130 and 135, Appellant intends to provide the missing antecedent basis. With regards to claim 133, Appellant intends to delete the recitation of the limitation "a form cutter mountable on said housing and movable by said drive means," thus curing any deficiency with the means-plus-function language in the claim.

**D. The Rejection Under 35 U.S.C. § 102(b) of Claims 1-3, 5-7, 13-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97, 100-102, 104-109, 111, 114-125, 128 and 130-138 Based on U.S. Patent No. 4,197,645 to Scheicher is Improper**

On pages 3-5 of the Office Action, claims 1-3, 5-7, 13-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97, 100-102, 104-109, 111, 114-125, 128 and 130-138 were rejected under 35 U.S.C. § 102(b) as being anticipated by Scheicher (U.S. Patent No. 4,197,645). This rejection is hereby respectfully traversed.

Under 35 U.S.C. § 102, the Patent Office bears the burden of presenting at least a prima facie case of anticipation. In re Sun, 31 USPQ2d 1451, 1453 (Fed. Cir. 1993) (unpublished). Anticipation requires that a prior art reference disclose, either expressly or under the principles of inherency, each and every element of the claimed invention. Id.. "In addition, the prior art reference must be enabling." Akzo N.V. v. U.S. International Trade Commission, 808 F.2d 1471, 1479, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986), cert. denied, 482 U.S. 909 (1987). That is, the prior art reference must sufficiently describe the claimed invention so as to have placed the public in possession of it. In re Donohue, 766 F.2d 531, 533, 226 USPQ 619, 621 (Fed. Cir. 1985). "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention." Id.

The Office Action explains the rejection under 35 U.S.C. §102 as follows:

> In regards to claims 1-3, 5-7 and 13-24, Scheicher discloses in Figs. 1-4 and 13-18, a milling apparatus or a device for preparing a space in human bone to receive an implant, which is also capable of preparing a space in a human spine to receive an insert if one desires to do so. Said milling apparatus comprises a drill head 11, a rotary form cutter 5, a drive means 40, elongate housing 3, said form cutter has a convex shape, a groove, and provided with a beveled gearing surface 37, the height of profile of the form cutter is approximately 9 mm (2.5-10mm), as disclosed in col. 17, line 56, said drive means having a pinion gear 39, and said cutter having a support shaft 8 which forms an angle approximately 96 degrees to the drive means 40, (and approximately 96 degrees which generally could be 90 degrees).
>
> The statement of intended use of the device for preparing a space in a human spine to receive and insert between adjacent vertebral bodies has been carefully considered, but is deemed not to impose any structural limitations on the claims patentably distinguishable over the Scheicher which is capable of being used as claimed if one desires to do so, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed articles from the prior art article satisfying the claimed structural limitations. *Ex Parte Marsham*, 23 U.S.P.Q.2d 1647 (1987).
>
> In regard to claims 25-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97, 100-102, 104-109, 111, 114, 125, 128, 130-139, Scheicher device disclose all limitations substantially as claimed, such as, the form cutter has at least one milling surface 5a, 5b, 5c (see Figs. 1-3) that is capable to create a contour in one of the adjacent vertebral bodies; the gear 39 of the drive means is configured to mate with corresponding teeth 39 on the cutter (see Figs. 5b, 13 and 14).

*See* Office Action, ¶ 7.

As set forth below, Appellants respectfully disagree with the pending rejection, and respectfully submits that pending independent claims 1, 15, 18, 25, 41, 47, 49, 67, 82, 97, 114, 120, 121, and 128, and 130-138 are patentable over the Scheicher reference.

1. The Scheicher Patent

Scheicher discloses a drilling apparatus for the preparation of bone cavities that includes a plurality of drills which are simultaneously driven in opposite direction with the cutting surfaces of each drill overlapping the cutting surfaces of at least one other drill to provide intersecting bone cavities. The drills may be driven by gearing located within the drill head or by

gearing located in an attachment suitable for connection to a conventional drill head having a single output drive. The drills may be disposed along a straight or curved line or may be disposed in a triangular relationship with the axis of rotation of one of the drills being transversely movable relative to the axis of rotation of another drill. *See* Scheicher, Abstract.

2. Improper Rejection of Claims 25-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97, 100-102, 104-109, 111, 114-125, 128, and 130-138

Regarding claims 25-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97, 100-102, 104-109, 111, 114-125, 128, and 130-138, the Office Action disregards the requirements for *prima facie* anticipation by outright ignoring numerous claim terms and limitations. Essentially, the Office Action glances over the terms and limitations of above claims by making vague and insufficient reference to the Scheicher by merely asserting that the "Scheicher device disclose (sic) all limitations substantially as claimed, such as, the form cutter has at least one milling surface 5a, 5b, 5c (see Figs. 1-3) that is capable to create a contour in one of the adjacent vertebral bodies; the gear 39 of the drive means is configured to mate with corresponding teeth 39 on the cutter (see Figs. 5b, 13 and 14)." Appellants respectfully submit that such an allegation is an improper "catch-all" assertion that falls far short of complying with the Office's burden to set forth a proper §102 rejection.

In fact -- with the exception of two limitations -- the "catch-all" phrase fails to identify which claim limitations of the referenced claims are purportedly disclosed by Scheicher, and where specifically in Scheicher such limitations may be found. Without this information Appellants are forced to speculate, making preparation of a complete and proper response virtually impossible. Board precedent clearly favors overturning such vague and equivocal rejections. *See e.g., Ex parte Gambogi*, 62 U.S.P.Q.2d 1209, 1212 (Bd. Pat. App & Inter. 2001)

("Rejection of claims in patent application under ... must be vacated and remanded, since patent examiner has ... not indicated what that prior art would have meant to person of ordinary skill in the art, since examiner has not referred to specific portions of each of cited references, and since rejection therefore requires both applicants and Board of Patent Appeals and Interferences to speculate....").

3. Alleged "Functional Language" Must be Given Patentable Weight

A cornerstone of the Office's anticipation rejection is its refusal to accord proper patentable weight to numerous recitations of the pending claims. In particular, the Office takes the position that certain claim recitation amount to functional limitations that allegedly do not impose any structural limitations on the claims, and thus cannot be relied upon to distinguish the claimed systems and methods from the Scheicher device. For example, the Office alleges that claim 1's preamble reciting "[a] device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies" cannot be given patentable, particularly given that the Scheicher devices read on the structural limitations of the claims. In support of its rejection, the Office relies on the decision of the Board in *Ex Parte Marsham*, 2 U.S.P.Q.2d 1647 (1987).

However, unlike the applicant in *Ex Parte Marsham*, Appellants have presented arguments and even submitted the testimony of one of ordinary skill in the art (See Appendix C--Declaration of Carlos Gil) stating that the Scheicher devices do not teach and suggest each and every limitation of the pending claims, and are <u>not</u> able to operate in the manner of the claimed devices. Contrary to established precedent, the Office has outright dismissed this testimony. **[WE NEED TO DISCUSS THE BYLAND AND HALLMAN CASES AND WHETHER WE SHOULD CITE TO THEM]**

Thus, Appellants respectfully submit that the Office's dismissal of these allegedly

"functional limitations" runs counter to established authority. Compelling Board and Federal Circuit precedent mandates that preamble recitations must be given patentable weight where, as here: (1) the preamble contributes to the definition of the claimed invention (e.g., adjacent vertebral body is referenced in the preamble and body of claim 25); (2) the preamble's relationship to the specification so requires (e.g., the preamble addresses or relates to one of the problems the specification makes clear is overcome by the invention (here, it is the inability of prior art tools and devices to effectively mill the surfaces of adjacent vertebrae)). Further, established precedent requires that "functional language" in the preamble and body of a claim be given patentable weight where, as here, such language is tied to clear structural limitations.

a. Preamble Recitations Must be Given Patentable Weight

Appellants believe that the pending claims patentably define over Scheicher even if the preamble is given no weight in construing the claim. Nonetheless, Appellants further respectfully submit that the Examiner has improperly refused to give weight to certain claim language, both in the preamble and in the body of the claims. The Federal Circuit has held that the preamble may limit the scope of a claim when, as here, the preamble contributes to the definition of the claimed invention. *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1350, 48 U.S.P.Q.2d 1225 (Fed. Cir. 1998). Indeed, where a term appears not only in the preamble, but is referenced in the body of the claim, that preamble and term may be found to be limiting. *Gerber Garment Technology Inc. v. Lectra Systems Inc.*, 916 F.2d 683, 689, 16 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1990); *see also Bell Comm. Research Inc. v. Vitalink Comm. Corp.*, 55 F.3d 615, 621, 34 U.S.P.Q.2d 1816, 1820 (Fed. Cir. 1995) (the preamble can be incorporated by reference because of language appearing later in the claim, making it a limitation of the claim.)

Further, a preamble may be construed to be limiting based on its relationship to the

description in the specification. *See, e.g., Applied Materials Inc. v. Advanced Semiconductor Materials*, 98 F.3d 1563, 40 U.S.P.Q.2d 1481 (Fed. Cir. 1996) (interpreting preamble recitation of "cold purge" to be limiting in light of the problem solved in the patent); *Bell Comm. Research Inc. v. Vitalink Comm. Corp.*, 55 F.3d at 621 ("Claim 6, as drafted and in light of the specification, is plainly limited such that it literally reads only on methods that transmit packets having both source and destination addresses"). In some cases, as here, the specification may make clear that the inventors were working on a ***particular problem relevant to the preamble***, such that the preamble gives life and meaning to the claimed invention. *See General Electric Co. v. Nintendo Co.*, 179 F.3d 1350, 1361, 50 U.S.P.Q.2d 1910, 1919 (Fed. Cir. 1999).

Appellants respectfully submit that under the authority of the case law enumerated above, the preambles of the various pending claims **should** be considered in construing the claim. Taking the preamble of claim 25 as an example, the terms and phrases used therein indicate that the preamble is more than just language of intended use, as the Examiner asserts. Indeed, the preamble of claim 25 comprises language contributing to the definition of the claimed invention, and must thus be given weight. For instance, the expression "adjacent vertebral bodies," which indicates the area within which the claimed invention is to be used to prepare a space, is further used in the body of the claim to specify exactly where the "at least one milling surface" is to create a surface contour. The Examiner cannot discard this limitation and apply the teachings of Scheicher (teaching a dental drill) to invalidate the pending claims.

Moreover, the specification makes clear that one of the problems overcome by the present invention is the inability of prior art tools and devices to effectively mill the surfaces of adjacent vertebrae. The Federal Circuit has clearly stated that the act of looking to the specification to determine whether a preamble has limiting effect is not only proper, but

required:

> No litmus test can be given with respect to when the introductory words of a claim, the preamble, constitute a statement of purpose for a device or are, in themselves, additional structural limitations of a claim.... The effect preamble language should be given can be resolved ***only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.***

*General Electric Co. v. Nintendo Co., Ltd.*, 179 F.3d 1350, 1361 (Fed. Cir. 1999) (quoting *Corning Glass Works v. Sumitomo Elec. U.S.A.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989).

In *General Electric Co. v. Nintendo Co., Ltd.,* the Federal Circuit, in determining whether the preamble would have limiting effect, considered the invention as ***described in the specification*** and stated as follows:

> Here, the '125 specification makes clear that the inventors were working on the particular problem of displaying binary data on a raster scan display device and not general improvements to all display systems. ***In light of the specification, to read the claim indiscriminately to cover all types of display systems would be divorced from reality.*** The invention so described is restricted to those display devices that work by displaying bits, which is not true with respect to all display systems recited in just the body of the claim. "Thus, we conclude that the claim preamble in this instance does not merely state a purpose or intended use for the claimed structure. Rather, those words do give 'life and meaning' and provide further positive limitations to the invention claimed."

*Id.*

Appellants respectfully submit that the Patent Office must reach the same conclusion in this case. A review of the entire pending patent application reveals that the apparatus disclosed and claimed must be able to fit within the area between two adjacent vertebrae and must be able to mill the adjacent surfaces thereof. *See e.g.,* Substitute Specification ¶ 12 ("It is an object of the instant invention to provide a drill head which can fit within the narrow space between two opposing vertebral bodies); ¶ 15 ("The instant invention overcomes the deficiencies of the prior art devices by providing a drill head with a narrow profile which can fit in the space between two

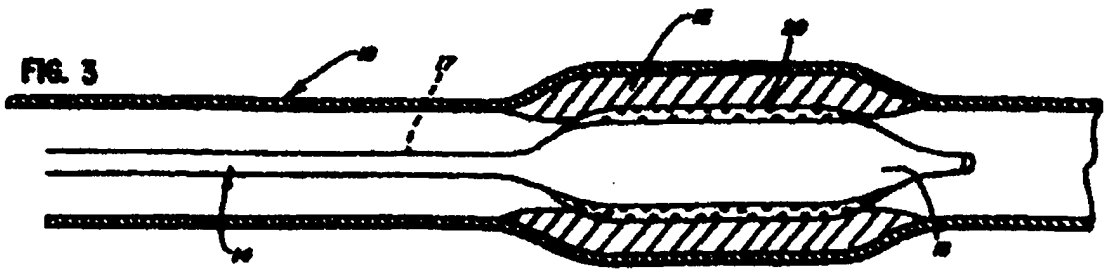
opposing vertebral bodies.") For the Examiner to ignore this critical distinction and to then broadly read the claims to cover any drilling device, in particular the dated dentist tool for drilling teeth described in Scheicher, in the words of the Federal Circuit, is to act "***divorced from reality***." Accordingly, in view of the above authority, the respective preambles of the pending claims do give 'life and meaning' to the claimed inventions and thus provide further positive limitations to the invention claimed. Appellants respectfully request that the Examiner reconsider and withdraw this rejection.

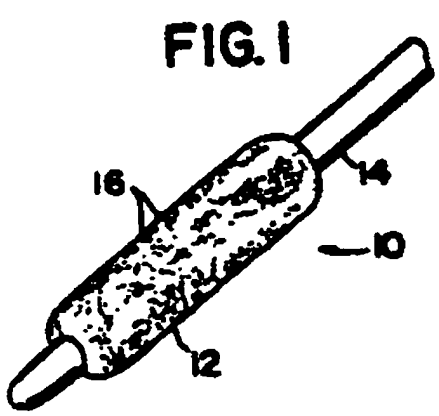
b. Functional Language is Tied to Structural Limitations and Therefore Must be Given Patentable Weight

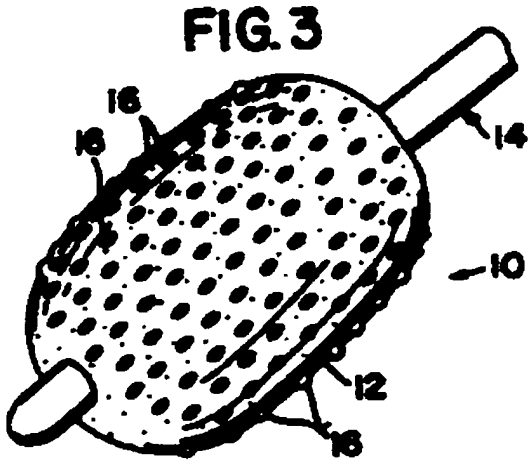
In addition, Appellants respectfully submit that functional language in the preamble and body of a claim must be given patentable weight where, as here, such language is tied to structural limitations. In *Rowe v Dror*, 42 USPQ2d 1550 (Fed. Cir. 1997), the Federal Circuit addressed the following claim:

> In a balloon angioplasty catheter of the type comprising a catheter body and a balloon positioned along the length of the catheter body, said balloon including means for remotely inflating and deflating said balloon; the improvement comprising:
>
> (a) a plurality of microcapsules on the exterior of said balloon, each of said microcapsules carrying a drug or combination of drugs for treatment or diagnostics within a body lumen when said catheter is positioned and inflated therewithin such that the drug or drugs may be released from said microcapsules.

The invention was illustrated in the figures as follows:






The prior art patent described a general purpose catheter with a swab or balloon (with microcapsules) for applying medicine into a body duct. Figure 12 below shows the head of a catheter with a tubular catheter sidewall (137) surrounding a medicated swab (144). The medicated swab (144) may extend out the end of the catheter (by the pushing action of a piston (140)) to apply medicine to internal body tissue. The reference teaches as well that the swab (144) could carry the medicine in microcapsules.

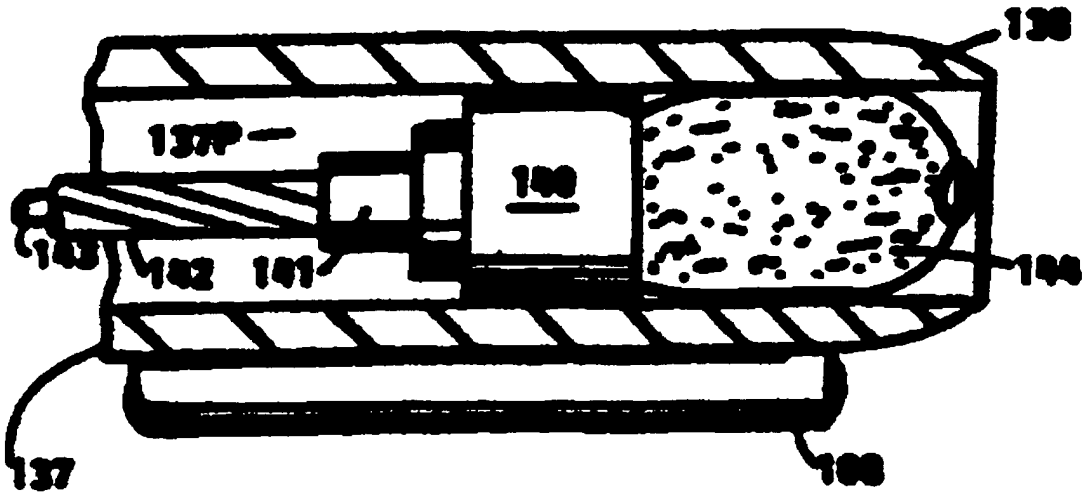



**FIG. 12**

Although the prior art did not illustrate a balloon catheter, it taught that the medicated

swab (144) in Figure 12 "may be replaced by an inflatable enclosure, such as a rubber finger or balloon, which is controllably inflated from within the catheter chamber or upon being projected therefrom as described." The Board found anticipation. On appeal Rowe contended that the Board erred by failing to treat "angioplasty" as a claim limitation. Rowe further argued that the prior art patent could not anticipate his claims because it discloses neither "a balloon positioned along the length of the catheter body" nor a "means for remotely inflating and deflating said balloon."

At issue was whether the recitation of a "balloon angioplasty catheter" served to further limit the claim and thereby distinguish the invention from the prior art which was directed to a general purpose catheter rather than to an angioplasty catheter. The court concluded that the phrase indeed imposed structural restrictions on the claim, noting, among other things, that the specification evinced a particular and distinct structural meaning for "balloon angioplasty catheter" that distinguished it from "balloon catheters" generally.

The court noted that an angioplasty catheter must be capable of "expand[ing] a stenosis in a coronary artery." The specification indicated that the pressure exerted against the vessel walls upon balloon inflation forces the medication into the stenosis. These and similar phrases limit the claimed "balloon angioplasty catheters" to catheters that can be inflated radially outward to dilate a narrowed region in a blood vessel.

Appellants respectfully submit that the alleged "functional language" of the pending claims presents an even more solid case than did the claim language at issue in *Rowe*. First, the pending claims recite both structure and function in the preambles and bodies of the claims rather than merely in the preamble, as was the case with *Rowe*. Second, as in *Rowe*, the specification of the pending application defines a function (*e.g.*, milling to enable insertion of a

prosthetic between adjacent vertebrae) that fully distinguishes the dental implant function of Scheicher. For example, pending independent claim 1 recites a form cutter having "a profile . . . of a height capable of being admitted into the space between two opposing vertebral bodies" which, as is explained below, Scheicher fails to disclose. **[ROB, NGO IS GIVING WEIGHT TO THE "CAPABLE" LANGUAGE AND ALLEGES THAT SCHEICHER DISCLOSES CUTTERS THAT ARE SPACED 9mm APART—SEE OUR RESPONSE BELOW]**

Another relevant decision of the Board (albeit unpublished) is *Sanada v. Reynolds*, 67 USPQ2d 1459, 1463 (BPAI 2003), holding -- consistent with CCPA, Federal Circuit and published Board precedent -- that there is nothing wrong with using functional claim language where such functional language further limits structure or composition already defined in the claim. **[WE SHOULD NOT CITE IF UNPUBLISHED]**

Thus, Appellants respectfully submit that there is clear precedent sanctioning the use of functional language that imposes structure on a claimed invention. Appellants respectfully submit that the alleged "functional language" (e.g., the preambles of the pending independent claims) inevitably impose structure on the claims as a whole given the express function described in the specification, namely, the milling of adjacent or opposing vertebrae to enable insertion of a predetermined endoprosthesis device or the preparation of a space in a human spine to receive an insert between adjacent vertebral bodies. In this regard, reference is made to the attached Appendix B which sets forth the language (in bold) that imparts clear structural and/or functional distinctions between the pending independent claims and the Scheicher reference.

In view of the above, Appellants respectfully request that the alleged "functional language" of the independent claims set forth in bold text in Appendix B be given patentable weight as required by clear and established precedent.

4. Structural Distinctions

Appellants respectfully submit that even without the alleged functional language, independent claims 1, 15, 18, 25, 41, 47, 49, 67, 82, 97, 114, 120, 121, and 128, and 130-138 are nonetheless structurally distinguishable from the Scheicher device. Each claim is addressed below.

a. Independent Claim 1

Regarding claim 1, the Office Action alleges that Scheicher discloses "a form cutter...capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined surface...wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies." The Office Action alleges that "the height of profile of the form cutter is approximately 9 mm (2.5-10mm), as disclosed in col. 17, line 56. Therefore, the Office alleges, "the form cutter is capable of being admitted into the space between two opposing vertebral bodies." The Office Action also alleges that Scheicher's disclosure in col. 1, lines 5-12 of "a drill head or a bone drill or milling cutter for preparing bone cavities into which a prosthesis elements can be inserted" reads on claim 1's limitation that the "drill head is capable for (sic) preparing the bone of two opposing vertebral bodies to accept an endoprosthesis device."

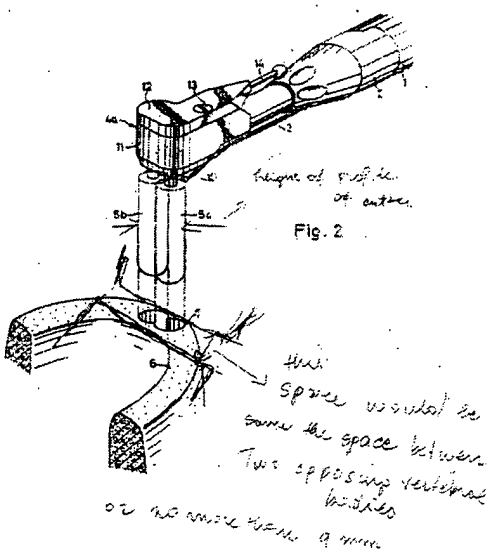
During prosecution, the Office offered two techniques in which the Scheicher device is alleged to perform like the claimed devices, namely: (1) by inserting the Scheicher drill heads *lengthwise* into the area between adjacent vertebral bodies (i.e., such that the drill heads are parallel to the surface of the adjacent vertebral bodies--see marked-up Figures 2 and 3 below), and (2) by drilling *through* a vertebral body to get into the area between adjacent vertebral bodies.

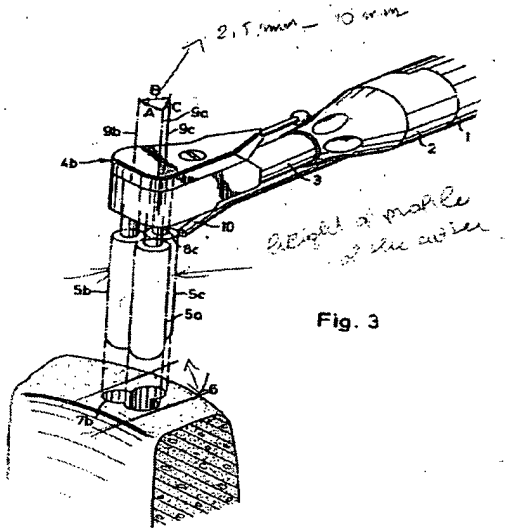
(i) Alleged Techniques for Using the Scheicher Device in the Manner Claimed are Not Possible

Appellants respectfully submit that neither of these techniques demonstrates that the Scheicher device has: (1) a form cutter having a profile capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined endoprosthesis surface shape, or (2) wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies.

The parallel or lengthwise technique is illustrated in marked-up Figures 2 and 3 below.[3] Figure 2, for example, shows the Scheicher drill heads entering the area between two adjacent vertebral bodies (depicted as mirror-image brackets "] ["). Figure 2 indicates -- in the Examiner's handwriting -- that the space between the two brackets "would be the same space between two adjacent vertebral bodies." Thus, the drill heads are inserted *lengthwise* into the area between the adjacent vertebral bodies such that the sides of the drill heads are parallel to the surfaces of the vertebral bodies. As shown, milling is accomplished along the length of drill heads 5b and 5c.

[3] Marked-up Figures 2 and 3 were submitted by the Examiner in support of the September 24, 2004 Office Action to purportedly demonstrate how the Scheicher device performs like the claimed systems and methods.




The Examiner indicates that the distance between drill heads 5b and 5c comprises the claimed "height" of the form cutter profile. However, marked-up Figure 3 clearly shows that the distance referred to by the Examiner -- either A, B, or C -- is the distance between the ***midpoint*** of any two shafts supporting drill heads 5a, 5b or 5c, and ***not***, as the Examiner alleges, the ***width*** of any two drill heads side-by-side. Appellants respectfully submit that such a distance would necessarily be greater than any of the distances A, B or C, thus casting great doubt that the drill heads of the Scheicher device: (1) are "capable of imparting a concaval-convex shape to the bone of vertebral bodies" as expressly recited in claim 1, or (2) could fit within the space defined by adjacent vertebral bodies "in order to create a surface contour in one of the adjacent vertebral bodies," as recited in claim 25, for example.

To fully rebut the Office's alleged use of the Scheicher device, Appellants filed the Declaration of Carlos Gil as part of Appellants' response to the Final Office Action of August 22, 2003. *See* Appendix C, Declaration of Carlos Gil ("Gil Declaration"). Mr. Gil is qualified as one of ordinary skill in the relevant art. *See, e.g.,* Gil Declaration, ¶'s 2-5. In particular, Mr. Gil, states that Scheicher fails to disclose each and every limitation of the pending claims and that the

Scheicher device is unable to operate in the manner of the claimed devices:

> In addition, none of the devices disclosed in the Scheicher patent could be used to perform like the devices disclosed and claimed in the present application. For example, the devices disclosed in the Scheicher patent could not achieve the stated objective of the present application, namely the development of an apparatus that could be used to drill in-between adjacent vertebral bodies. Indeed, given the sensitive nature of the human spine, it is ***impossible*** to use the devices described in the Scheicher patent, or any dentist drill for that matter, to achieve the apparatus structure and functionality disclosed and claimed in the present application.

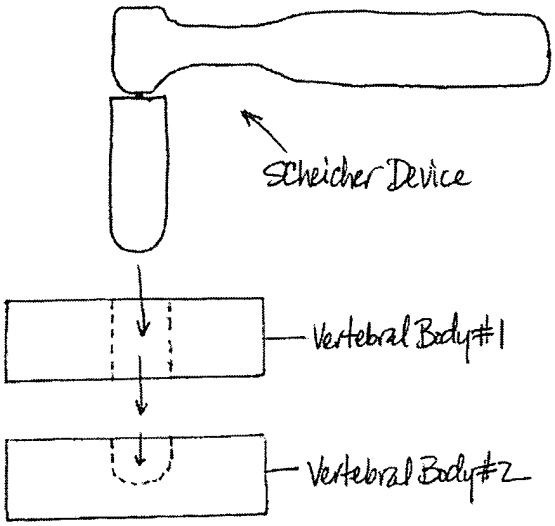
(emphasis in original).

Further, Mr. Gil states that the purported application of the Scheicher device is not practical because the user would not be able to create a predetermined surface contour in an end plate of an adjacent vertebral body. *See* Gil Declaration, ¶ 15. Mr. Gil further stated that upon coming in contact with the surface of the vertebral body, the tendency of the drill head of the Scheicher device would be to roll off, much like a wheel does when coming in contact with a hard, solid surface. *Id.* Mr. Gil stated that this lack of control renders the Scheicher device a useless (and potentially life threatening) instrumentality for performing the type of spinal surgery contemplated by the claimed devices. *Id*

In addition, Mr. Gil states that Sheicher fails to disclose a form cutter "capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined surface shape ... wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies," as set forth in independent claim 1. *See* Gil Declaration, ¶11.

The second technique proposed by the Examiner was discussed during an Examiner Interview that was held on November 4, 2004. In this technique, the Scheicher device is used to drill ***through*** one of the adjacent vertebral bodies (from top to bottom, for example) so that the

drill heads may enter the space between adjacent bodies and eventually come into contact with the surface of the ***other*** vertebral body. According to the Examiner, it is irrelevant whether a live patient could survive or tolerate such a procedure, or whether such an approach is even possible on a live subject.[4] The Examiner asserts that the technique would result in the creation of a surface contour in one of the adjacent vertebral bodies, regardless of what happens to the live patient. Below is Appellants' depiction of the technique:




Clearly, the above technique demonstrates that the alleged form cutter profile of Scheicher is not of a height capable of being admitted into the space between two opposing vertebral bodies, as required by independent claim 1.

In view of the above, Appellants respectfully submit that Scheicher fails to teach or suggest: (1) a form cutter having a profile capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined endoprosthesis surface shape, or (2) wherein the profile of the form cutter is of a height capable of being admitted into the space between two

[4] Of course, if the alleged "functional language" is given patentable weight -- as it should -- the effect on a live patient would be relevant.

opposing vertebral bodies. Accordingly, independent claim 1 is structurally patentable over Scheicher.

b. Independent Claim 15

Independent claim 15 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) "[a] drill head for preparing the bone of two opposing vertebral bodies to accept the concaval-convex shape of an endoprosthesis," and/or (2) a form cutter having a support shaft capable of imparting a concave shape to the bone of vertebral bodies," and/or (3) wherein the angle between the support shaft of the form cutter and the drive shaft is approximately 96°." Appellants respectfully submit that the Examiner's assertion that approximately 96 degrees could "generally be 90 degrees" is incorrect. Paragraph 32 of the substitute specification clearly distinguishes a right angle (90 degrees) from 96 degrees, stating that the latter is able to "provide a designed orientation to the vertebral bone surface being milled":

> As shown in Figure 2, the form cutter 29 is ***not necessarily oriented at a right angle*** with respect to the drive shaft 54. In the illustrated device, the angle between the support shaft 51 of the form cutter 29 and the device shaft 54 is ***approximately 96° to provide a designed orientation to the vertebral bone surface being milled***.

*See,* Page 6, ¶ 32 of the Substitute Specification (emphasis added). Appellants respectfully submit that the above excerpt makes it clear that 90 degrees is not the same as 96 degrees.

Accordingly, Appellants respectfully submit that independent claim 15 is structurally patentable over Scheicher.

c. Independent Claim 18

Independent claim 18 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) "[a] milling apparatus for preparing surfaces of two opposing vertebral

bodies to accept a predetermined shape of an endoprosthesis," (2) "a rotary form cutter having a profile matching the predetermined shape of the endoprosthesis, the rotary form cutter rotatable about a rotation axis," and/or (3) "wherein the rotary form cutter cuts an imparted shape into the surfaces of the vertebral bodies that matches the predetermined shape of the endoprosthesis by rotation of the rotary form cutter."

d. Independent Claim 25

Independent claim 25 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) "[a] device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies," and/or (2) "said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means."

e. Independent Claim 41

Independent claim 41 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) "[a] form cutter for preparing a space between adjacent vertebral bodies to receive an insert," (2) "at least one milling surface and being mountable on a device capable of moving said form cutter to cause said at least one milling surface to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies," and/or (3) "said at least one milling surface having a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis shape of the insert to be received between the adjacent vertebral bodies."

f. Independent Claim 47

Independent claim 47 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) "[a] device for preparing a space in a human spine across a disc space

and into the end plates of adjacent vertebral bodies to receive an interbody spinal insert," (2) "said form cutter has at least one milling surface selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies as said form cutter is moved by said drive means," and/or (3) "said milling surface is configured to have a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of the interbody spinal insert."

g. Independent Claim 49

Independent claim 49 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) "[a] device for preparing a space to receive an interbody insert within and between the adjacent surfaces of vertebral bodies disposed adjacent a disc space," (2) "said milling surface has a profile that imparts a shape to the bone of the vertebral bodies which mates with the predetermined endoprosthesis surface shape of the insert to be implanted," (3) "said milling surface has a configuration adapted to remove bone from the vertebral bodies to prepare the vertebral bodies to receive the insert," and/or (4) "said milling surface of said form cutter is configured to be generally parallel to a receiving surface that is formed on one of the vertebral bodies by said device."

h. Independent Claim 67

Independent claim 67 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) "[a] device for preparing a space in the human spine to receive an insert between adjacent vertebral bodies," and/or (2) "said form cutter having at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means."

i. Independent Claim 82

Independent claim 82 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) "[a] device for preparing a space to receive an insert between adjacent vertebral bodies," and/or (2) "said form cutter has at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means."

j. Independent Claim 97

Independent claim 97 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) "[a] device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies," and/or (2) "said form cutter has at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means."

k. Independent Claim 114

Independent claim 114 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) "[a] form cutter for preparing a space between adjacent vertebral bodies to receive an insert," (2) "said form cutter having: at least one milling surface and being mountable on a device capable of moving said form cutter to cause said at least one milling surface to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies," (3) "said at least one milling surface having a profile that imparts a shape to the bone on the vertebral bodies which mates with a predetermined endoprosthesis surface shape of the insert to be received between the adjacent vertebral bodies," (4) "said at least one milling surface having a perimeter that is at least in part arcuate," and/or (5) "said form cutter having a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine."

l. Independent Claim 120

Independent claim 120 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) "[a] device for preparing a space in a human spine across a disc space and into the end plates of adjacent vertebral bodies to receive an interbody spinal insert," (2) "said form cutter having a milling surface selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies as said form cutter is moved by said drive means in a plane generally parallel to the predetermined surface contour to be formed in said vertebral body," and/or (3) "said milling surface being configured to have a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of said interbody spinal insert."

m. Independent Claim 121

Independent claim 121 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) "[a] form cutter for preparing a space between adjacent vertebral bodies to receive an insert," (2) "said at least one top milling surface of said moving form cutter being capable of removing bone from an end plate of at least one of said adjacent vertebral bodies to create at least one surface in said end plate having a predetermined contour," (3) "said at least one top milling surface having a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of said insert to be received between said adjacent vertebral bodies," and (4) "said form cutter having a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine."

n. Independent Claims 128

Independent claim 128 is substantially the same as claim 25 except that it recites a form

cutter that has a concaval-convex cutting surface.[5]

o. Independent Claim 130

Independent claim 130 recites a "***single***" form cutter. Appellants respectfully submit that such a device is distinguishable from the Scheicher device because the latter includes a "***plurality***" of drills or abrading elements. For example, the Scheicher abstract expressly recites "a drilling apparatus for the preparation of bone cavities includes a ***plurality*** of drills which are simultaneously driven in opposite direction with the cutting surfaces of each drill overlapping the cutting surfaces of at least one other drill to provide intersecting bone cavities." *See* Scheicher Patent, Abstract (emphasis added). Scheicher further states that "[t]he drill head according to the invention for attachment of bone drills or cutters . . . is characterized by a mounting for ***at least two cutters*** having staggered aces or rotation, and by a driving mechanism for their joint operation." *See* Scheicher Patent, Col. 2, lines 18-23 (emphasis added).

Scheicher requires a plurality of drills in order to achieve several advantages described in the patent, which include:

> The drill head according to the invention ***makes it possible to drill simultaneously with several cutters***, whereby with a suitable refinement of the cutters the drill holes can overlap. Since the rotational axes of the individual cutters are positioned accurately with respect to one another, one obtains defined drill holes opening into one another at least in the upper region and which, after removal, if necessary, of webs of bone tissue remaining between them, can form the desired bone cavities intended for insertion of prosthetic elements.
>
> There is a further advantage in that any ***shifting of the individual cutter is avoided*** even when the bone tissue is very soft or brittle at one point, ***since there is at least one other cutter*** to take over the guidance in such a case.

[5] This limitation refers to the form-cutter's ability to form concaval or convex surfaces on adjacent vertebral bodies. The actual shape of the form cutter surface may be as described in the specification. *See, e.g.,* Page 5, ¶ 26 of the Substitute Specification ("To provide a drill head which can prepare the bone of the two opposing vertebral bodies to accept the concaval-convex shape of an endoprosthesis, the illustrated form cutter has a convex milling surface.")

> The drill head according to the invention ***makes possible the production of a large number of bone cavities with defined but never-the-less varying shape since in the individual mounting of the drill head cutters of varying length, varying diameter and varying character of head can be used simultaneously in arbitrary combination***. In this way bone cavities with a defined external contour, but being of varying depth in different regions can be made. ***The overlapping drill holes result in the side walls dumbbell-like in cross section and where the implant is of corresponding shaping this guarantees an optimal and twist-free lodgement for the implant in the jaw***, similar to that assumed by the natural tooth in the jaw.

*See* Scheicher Patent, Col. 2, lines 17-52 (emphasis added).

Accordingly, Appellants respectfully submit that Scheicher does not disclose -- and thus cannot anticipate -- a device having a "***single***" form cutter. *See, e.g., Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A prior art reference anticipates a claim only if the reference discloses, either expressly or inherently, ***every limitation of the claim***."); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989) ("The ***identical invention*** must be shown in as complete detail as is contained in the ... claim."); *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565, 1571 (Fed. Cir. 1986) ("Absence from the reference of ***any*** claimed element negates anticipation.")

In view of the above, Appellants respectfully submit that new claim 130 is allowable over the Scheicher reference.

p. Independent Claim 131

Independent claim 131 recites a form cutter having a "convex shape so as to prepare the bone of vertebral bodies to accept the concaval-convex shape of an endoprosthesis," and that "perform milling action in a direction angled away from the direction of head entry into a space between opposed bodies." Appellants respectfully submit that claim 131 is distinguishable from Scheicher device because the latter cannot at once: (1) have a concave surface, ***and*** (2) mill in a

direction angled away from the direction of head entry of the concave milling surface. The methods proposed by the Examiner illustrate the point. For example, if the drill heads of the Scheicher device are inserted *lengthwise* into the space between adjacent bodies, then the milling surface would not be concave. However, if the drill heads go ***through*** an adjacent vertebral body in order to enter the space between adjacent vertebral bodies, then the milling will not be in a direction angled away from the direction of head entry of the milling surface. Thus, the Scheicher device cannot satisfy both limitations. Accordingly, Appellants respectfully submit that claim 131 is allowable over the Scheicher reference.

q. Independent Claim 132

Independent claim 132 recites a form cutter having "a profile selected to impart a shape in the bone of the vertebral bodies that mates with the endoprosthesis device." Appellants respectfully submit that the Scheicher reference does not teach or suggest a form cutter having a profile selected to impart a shape in the bone of the vertebral bodies that mates with an endoprosthesis device. In fact, in his declaration Mr. Gil expressly states none of the Scheicher devices includes a form cutter "capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined surface shape ... wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies." *See*, Gil Declaration, ¶ 11.

r. Independent Claim 133

Independent claim 133 recites "***means for*** preparing a space in a human spine to receive the endoprosthesis device between adjacent vertebral bodies, said space comprising a surface contour in at least one of the adjacent vertebral bodies." A prior art reference anticipates a means-plus-function element literally if it performs the ***identical function*** recited in the claim

***and*** incorporates the corresponding structure disclosed in the specification for performing that function or an equivalent thereof. *Pennwalt Corp. v. Durand-Wayland, Inc.,* 833 F.2d 931, 934 (Fed. Cir. 1987) (en banc); *Cortland Line Co., Inc. v. Orvis Co., Inc.,* 203 F.3d 1351, 1358 (Fed. Cir. 2000).

Appellants respectfully submit that the Scheicher device neither performs the identical function of preparing a space in a human spine to receive the endoprosthesis device between adjacent vertebral bodies, nor does it disclose the identical structure (or its equivalent) for performing such function. In fact, the pending application mentions that drilling devices like the Scheicher device are incapable of performing like the claimed devices:

> In order to place the above endoprosthesis in a patient's spine, the bone of the two opposing vertebral bodies must be prepared in such a manner so as to accept the concaval-convex shape of endoprosthesis. However, ***currently available drill heads are not always capable of being fit into the narrow space between two opposing vertebral bodies***. Further, the narrow space between two opposing vertebral bodies cannot always be expanded to allow admittance of currently available drill heads.
>
> Thus, it is an object of the instant invention to provide a ***drill head which can prepare the bone of two opposing vertebral bodies to accept the concaval-convex shape of an endoprosthesis***.

*See* Page 3, ¶s 11 and 12 of the Substitute Specification.

Even if the Scheicher device was able to perform the claimed function, it does not disclose the identical structure disclosed in the pending application (or one equivalent thereto) for performing such function. The corresponding structure for performing the function of preparing a space in a human spine to receive the endoprosthesis device between adjacent vertebral bodies is described in the application as follows:

> To provide a drill head which can prepare the bone of the two opposing intervertebral bodies to accept the concaval-convex shape of an endoprosthesis, the illustrated form cutter 29 has a ***convex milling surface 42***. This convex

surface 42 of the form cutter 29 functions to provide the bone of a vertebral body ***with a mating shape complementary to the concaval-convex shape of the endoprosthesis*** which is the subject of co-pending U.S. patent application Ser. No. 08/681,230. As illustrated, this ***tool drill or milling head can mill in a direction angled away from the direction of device entry into the space between the intervertebral bodies***. That edge 44 provides the cutter 29 with the ability to cut in the direction of tool entry into the space between two opposed vertebral bodies.

The form cutter 29 further includes an ***outwardly extending edge 44*** about its perimeter. In addition, the undersurface 47 of the form cutter 29 may be provided with a ***beveled gearing surface 49***. Alternately, the beveled gearing surface 49 may be provided about the undersurface of the upstanding edge.

The form cutter 29 is provided with a ***shaft 51*** extending perpendicularly from its undersurface. The form cutter 29 is supported within the housing 31 by the cooperation between the shaft 51 and the shaft support 37. This arrangement permits the form cutter 29 to be removed from the housing 31 by separating the shaft 51 from the shaft support 37. Thus, when the cutter dulls, it can be replaced with a new cutter to ensure accurate and effective performance of the drill head.

In order to provide a drill head which can fit within the narrow space between two opposing intervertebral bodies in accordance with the invention, the ***maximum height of the illustrated form of the cutter portion 22 of the drill head 20 is nine millimeters***. Providing the bevel gearing surface 49 on the form cutter 29 allows the drill head 20 to be manufactured with such a narrow profile. This ***arrangement eliminates the need for a separate gear and form cutter which would likely add to the height of the drill head***. Because of its profile, the drill head 20 of the present invention can fit in the narrow space between two opposing intervertebral bodies in the cervical spine of a patient.

*See* ¶ s 20-23 of the Original Application (emphasis added).

Appellants respectfully submit that the Scheicher reference does not disclose a form cutter that is capable of preparing a space in a human spine to receive the endoprosthesis device between adjacent vertebral bodies, nor does it disclose a form cutter having the identical structure described above (or one equivalent thereto).

In view of the above, Appellants respectfully submit that independent claim 133 is allowable over the Scheicher reference.

s. Independent Claim 134

Independent claim 134 recites a form cutter that has "at least one ***vertebral body surface contour*** milling surface." Appellants respectfully submit that the Scheicher device does not include a vertebral body surface contour milling surface. Accordingly, Appellants respectfully submit that new independent claim 134 is allowable over the Scheicher reference.

t. Independent Claims 135-138

Independent claim 135 recites that the profile of the form cutter: (1) "is of a height capable of being admitted into the space between two opposing vertebral bodies," and (2) "rotate[s] about a shaft extending perpendicularly from its undersurface and the space between said opposing vertebral bodies." Appellants respectfully submit that such a device is distinguishable from the Scheicher device. Scheicher, for example, does not disclose a device having a form cutter that ***both***: (1) rotates about a shaft extending perpendicularly from its undersurface and the space between said opposing vertebral bodies, ***and*** (2) is of a height capable if being admitted into the space between two opposing vertebral bodies. Thus, if the Scheicher device is turned sideways to mill the surface of a vertebral body along the length of a drill head, it would not then "rotate about a shaft extending perpendicularly from its undersurface and the space between said opposing vertebral bodies," as expressly required by claim 135. Similarly, if the other technique is used -- i.e., drilling ***through*** one of the adjacent vertebral bodies -- the height of the form cutter's profile would not be such that it is capable of being admitted into the space between two opposing vertebral bodies. Moreover, the head of the form cutter would not be performing a "milling action in a direction ***angled away*** from the direction of head entry," as required by claim 135.

Independent claim 136 recites that the form cutter profile has at least one milling surface

that is "positioned to mill in a direction perpendicular to said elongated shaft portion." Appellants respectfully submit that the Scheicher devices do not include a milling surface that is positioned to mill in a direction perpendicular to an elongated shaft portion.

Independent claim 137 recites that the "surface contour [is] generally parallel to said elongated shaft portion." Appellants respectfully submit that the Scheicher devices do not create surface contours that are generally parallel to the elongated shaft portion.

Independent claim 138 recites that the "at least one milling surface [is] entirely within an area formed by the adjacent vertebral bodies during milling." Appellants respectfully submit that the Scheicher devices do not teach or suggest "milling surfaces" that are entirely within the area formed by adjacent vertebral bodies during milling."

In view of the above, Appellants respectfully submit that claims 135-138 are allowable over the Scheicher reference.

Appellants respectfully submit that, at least for the reasons set forth above, independent claims 1, 15, 18, 25, 41, 47, 49, 67, 82, 97, 114, 120, 121-138 are allowable over Scheicher.

5. Dependent Claims

Claims 2-14, 16-17, 19-24, 26-40, 42-46, 48, 50-61, 68-81, 83-96, 98-113, and 115-119 are dependent upon independent claim 1, 15, 18, 25, 41, 47, 49, 67, 82, 97, 114, or 121. Thus, since independent claims 1, 15, 18, 25, 41, 47, 49, 67, 82, 97, 114, and 121 should be allowable as discussed above, claims 2-14, 16-17, 19-24, 26-40, 42-46, 48, 50-61, 68-81, 83-96, 98-113, and 115-119 should also be allowable at least by virtue of their dependency on independent claims 1, 15, 18, 25, 41, 47, 49, 67, 82, 97, 114, or 121.

In view of the foregoing, it is respectfully requested that the aforementioned anticipation rejection of claims 1-3, 5-7, 13-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-

97, 100-102, 104-109, 111, 114-125, 128, and 130-138 be withdrawn

Respectfully submitted,

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## APPENDIX A - Pending Claims

1. (Previously Presented) A drill head for preparing the bone of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis comprising:

a form cutter having a profile capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined endoprosthesis surface shape;

drive means for providing a driving force to the form cutter, and

means for housing the form cutter and the drive means,

wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies.

2. (Previously Presented) The drill head of Claim 1 wherein the form cutter has a convex shape.

3. (Previously Presented) The drill head of Claim 2 wherein the form cutter is provided with a beveled gearing surface.

4. (Previously Withdrawn) The drill head of Claim 2 wherein the form cutter is provided with a groove about its perimeter.

5. (Previously Presented) The drill head of Claim 1 wherein the drive means comprises a drive shaft operatively coupling the form cutter to a drive source.

6. (Previously Presented) The drill head of Claim 5 wherein a distal end of the drive shaft is provided with a pinion gear which cooperates with the form cutter to impart a rotary motion to the form cutter.

7. (Previously Presented) The drill head of Claim 5 wherein a proximal end of the drive shaft is provided with a coupling means for coupling the drive shaft to the drive source.

8. (Previously Withdrawn) The drill head of claim 1 wherein the form cutter has a convex shape.

9. (Previously Withdrawn) The drill head of claim 8 wherein the belt loops about the perimeter of the form cutter.

10. (Previously Withdrawn) The drill head of Claim 9 wherein the drive means further comprises a drive shaft operatively coupled to the belt.

11. (Previously Withdrawn) The drill head of Claim 10 wherein the drive shaft is provided with a pulley about which the belt is looped.

12. (Previously Withdrawn) The drill head of Claim 11 wherein the drive shaft is further provided with a coupling means for coupling the drive shaft to the drive source.

13. (Previously Presented) The drill head of Claim 1 wherein the housing is provided with attachment means for attaching the drill head to a drive source.

14. (Previously Presented) The drill head of Claim 1 wherein the maximum height of the profile of the form cutter is approximately nine millimeters.

15. (Previously Presented) A drill head for preparing the bone of two opposing vertebral bodies to accept the concaval-convex shape of an endoprosthesis comprising:

a form cutter having a support shaft capable of imparting a concave shape to the bone of vertebral bodies;

drive means for providing a driving force to the form cutter, the drive means including a drive shaft; and

means for housing the form cutter and the drive means,

wherein the angle between the support shaft of the form cutter and the drive shaft is approximately 96°.

16. (Previously Presented) The drill head of Claim 15 wherein the form cutter has a predetermined profile.

17. (Previously Presented) The drill head of Claim 16 wherein the maximum height of the profile of the form cutter is approximately nine millimeters.

18. (Previously Presented) A milling apparatus for preparing surfaces of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis comprising:

a rotary form cutter having a profile matching the predetermined shape of the endoprosthesis, the rotary form cutter rotatable about a rotation axis;

a drive having proximal and distal ends, the drive operatively coupled to the rotary form cutter at the distal end to provide a force for rotating the rotary form cutter; and

an elongate housing containing the rotary form cutter and the drive, the elongate housing having a longitudinal axis in the elongate direction;

wherein the rotary form cutter cuts an imparted shape into the surfaces of the vertebral bodies that matches the predetermined shape of the endoprosthesis by rotation of the rotary form cutter.

19. (Previously Presented) The milling apparatus according to claim 18, wherein the profile of the rotary form cutter contained within the housing is configured to fit into a space between the two opposing vertebral bodies.

20. (Previously Presented) The milling apparatus according to claim 19, wherein the profile of the rotary form cutter contained within the housing is not more than approximately nine millimeters in height.

21. (Previously Presented) The milling apparatus according to claim 18, wherein the rotation axis of the rotary form cutter is transverse to the longitudinal axis of the elongate housing.

22. (Previously Presented) The milling apparatus according to claim 21, wherein the angle between the rotation axis and the longitudinal axis is approximately 96 degrees.

23. (Previously Presented) The milling apparatus according to claim 18, wherein the rotary form cutter is provided with a gear surface and the drive is provided with a gear at the distal end, and wherein the drive is coupled to the rotary form cutter by intermeshing the gear surface with the gear.

24. (Previously Presented) The milling apparatus according to claim 18, wherein the predetermined shape is a concaval-convex shape.

25. (Previously Presented) A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

26. (Previously Presented) The device of claim 25, wherein said housing is fixedly connected to said elongated shaft portion.

27. (Previously Presented) The device of claim 25, wherein:

said housing includes a shaft support; and

said form cutter includes a form cutter shaft configured to fit within said shaft support of said housing.

28. (Previously Presented) The device of claim 25, wherein said at least one milling surface is configured such that it is operated in a plane generally parallel to the surface contour formed in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

29. (Previously Canceled)

30. (Previously Presented) The device of claim 25 including drive means that operatively couples said form cutter to said drive source.

31. (Previously Presented) The device of claim 30, wherein:

the drive means comprises a drive shaft having a proximal end and a distal end;

said drive shaft is adapted to be received in said elongated shaft portion;

the distal end of said drive shaft is operatively coupled to said form cutter to move said form cutter; and

the proximal end of said drive shaft is operatively coupled to said drive source.

32. (Previously Presented) The device of claim 25, wherein said drive means is disposed at least in part in said elongated shaft portion.

33. (Previously Presented) The device of claim 25, wherein:

the device includes a drive shaft disposed within said elongated shaft portion;

said drive shaft is rotatably driven by said drive source;

said drive shaft has a gear at its distal end; and

said gear is configured to mate with corresponding teeth on said form cutter.

34. (Previously Presented) The device of claim 33, wherein:

said form cutter includes at least one top milling surface and a bottom surface;

said bottom surface is provided with a beveled gearing surface;

said beveled gearing surface engages teeth on said gear; and

said gear and said beveled gearing surface cooperate to rotate said form cutter as said drive shaft is rotatably driven.

35. (Previously Presented) The device of claim 25, wherein said form cutter is driven in rotary motion by said drive means.

36. (Canceled)

37. (Previously Presented) The device of claim 25, wherein:

said housing includes a surface formed on a side of said housing opposite said milling surface; and

said surface is configured to allow a surgeon to increase the pressure of said milling surface against the one of the adjacent vertebral bodies.

38. (Previously Presented) The device of claim 25, wherein said form cutter includes a leading edge configured as a bone cutting surface.

39. (Previously Presented) The device of claim 36, wherein at least one of said at least two milling surfaces of said form is convex.

40. (Previously Presented) The device of claim 36, wherein at least one of said at least two milling surfaces of said form cutter is tapered outwardly from a front surface of said form cutter.

41. (Previously Presented) A form cutter for preparing a space between adjacent vertebral bodies to receive an insert, said form cutter having:

at least one milling surface and being mountable on a device capable of moving said form cutter to cause said at least one milling surface to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies,

said at least one milling surface having a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis shape of the insert to be received between the adjacent vertebral bodies.

42. (Previously Presented) The form cutter of claim 41, wherein said form cutter has a top surface and a bottom surface.

43. (Previously Presented) The form cutter of claim 42, wherein at least one of said top surface and said bottom surface is a milling surface.

44. (Previously Presented) The form cutter of claim 41, wherein said form cutter has a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine.

45. (Previously Presented) The form cutter of claim 42, wherein at least one of said top surface and said bottom surface of said form cutter comprises a convex surface.

46. (Previously Presented) The form cutter of claim 42, wherein at least one area of said top surface and said bottom surface of said form cutter is tapered outwardly from the front surface of said form cutter.

47. (Previously Presented) A device for preparing a space in a human spine across a disc space and into the end plates of adjacent vertebral bodies to receive an interbody spinal insert, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source for powering said drive means;

a form cutter mountable on said housing; and

a coupling means for connecting and imparting motion from said drive means to said form cutter,

wherein:

said form cutter has at least one milling surface selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies as said form cutter is moved by said drive means; and

said milling surface is configured to have a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of the interbody spinal insert.

48. (Previously Presented) The device of claim 47, wherein:

said drive means moves said form cutter in a plane generally parallel to the predetermined surface contour to be formed in at least one of the end plates of the adjacent vertebral bodies; and

the movement of said form cutter is rotary.

49. (Previously Presented) A device for preparing a space to receive an interbody insert within and between the adjacent surfaces of vertebral bodies disposed adjacent a disc space, said device comprising:

an elongated shaft containing at least a portion of a drive means;

a housing positioned at the distal end of said elongated shaft portion; and

a form cutter disposed on said housing and operably connected to said drive means to be driven thereby,

wherein:

said form cutter has a milling surface;

said milling surface has a profile that imparts a shape to the bone of the vertebral bodies which mates with the predetermined endoprosthesis surface shape of the insert to be implanted;

said milling surface has a configuration adapted to remove bone from the vertebral bodies to prepare the vertebral bodies to receive the insert; and

said milling surface of said form cutter is configured to be generally parallel to a receiving surface that is formed on one of the vertebral bodies by said device.

50. (Previously Presented) The device of claim 49, wherein said form cutter includes first and second outwardly facing milling surfaces.

51. (Previously Canceled)

52. (Previously Presented) The device of claim 49, wherein said form cutter has at least one milling surface having a convex configuration.

53. (Previously Presented) The device of claim 49, wherein:

said form cutter includes outwardly facing first and second milling surfaces; and

said outwardly facing first and second milling surfaces are inclined relative to one another.

54. (Previously Presented) The device of claim 50, wherein said outwardly facing first and second milling surfaces are inclined with respect to each other.

55. (Previously Presented) The device of claim 49, wherein said drive means is adapted to produce a rotary movement of said form cutter about an axis generally perpendicular

to a longitudinal axis of said elongated shaft portion and a general plane of the vertebral end plate.

56. (Previously Presented) The device of claim 49, wherein said drive means is powered by a drive source.

57. (Previously Presented) The device of claim 49, wherein said housing has a surface opposite said milling surface of said form cutter for bearing against the vertebral body on the opposite side of the disc space.

58. (Canceled)

59. (Previously Presented) The device of claim 49, wherein said device is sterilizable for use in surgery.

60. (Previously Presented) The device of claim 49, wherein said form cutter is detachable from said housing.

61. (Previously Presented) The device of claim 49, including a rotatable drive shaft disposed within said elongated shaft portion, said rotatable drive shaft being operably connected to said drive means and to said form cutter.

62-66. (Canceled)

67. (Previously Presented) A device for preparing a space in the human spine to receive an insert between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means;

a form cutter mountable on said housing and movable by said drive means;

said form cutter having at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means;

said drive means including a drive shaft disposed within said elongated shaft portion;

said drive shaft being rotatably driven by said drive means; and

said drive shaft being operably coupled to said form cutter.

68. (Previously Presented) The device of claim 67, wherein

said drive shaft has a gear at its distal end

said gear is configured to engage corresponding teeth on said form cutter;

said gear and said teeth are configured such that said form cutter is rotated as said drive shaft is rotated by said drive means.

69. (Previously Presented) The device of claim 67, wherein said housing is fixedly connected to said elongated shaft portion.

70. (Previously Presented) The device of claim 67, wherein:

said housing includes a shaft support; and

said form cutter includes a form cutter shaft configured to fit within said shaft support of said housing.

71. (Previously Presented) The device of claim 67, wherein said at least one milling surface is configured such that it is operated in a plane generally parallel to the surface contour formed in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

72. (Previously Canceled)

73. (Previously Presented) The device of claim 67 including drive means that operatively couples said form cutter to said drive source.

74. (Previously Presented) The device of claim 73, wherein:

said drive means comprises a drive shaft having a proximal end and a distal end;

said drive shaft is adapted to be received in said elongated shaft portion;

the distal end of said drive shaft is operatively coupled to said form cutter to move said form cutter, and

the proximal end of said drive shaft is operatively coupled to said drive source.

75. (Previously Presented) The device of claim 67, wherein said drive means is disposed at least in part in said elongated shaft portion.

76. (Previously Presented) The device of claim 67, wherein said form cutter is driven in rotary motion by said drive means.

77. (Canceled)

78. (Previously Presented) The device of claim 67, wherein:

said housing includes a surface formed on a side of said housing opposite said milling surface; and

said surface is configured to allow a surgeon to increase the pressure of said milling surface against the one of the adjacent vertebral bodies.

79. (Previously Presented) The device of claim 67, wherein said form cutter includes a leading edge configured as a bone cutting surface.

80. (Previously Presented) The device of claim 67, wherein said at least one milling surface of said form cutter is convex.

81. (Previously Presented) The device of claim 68, wherein at least one of said at least two milling surfaces of said form cutter is tapered outwardly from a front surface of said form cutter.

82. (Previously Presented) A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means;

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means ; and

said housing has a surface formed on a side of said housing opposite said milling surface.

83. (Previously Presented) The device of claim 82, wherein said housing is fixedly connected to said elongated shaft portion.

84. (Previously Presented) The device of claim 82, wherein:

said housing includes a shaft support; and

said form cutter includes a form cutter shaft configured to fit within said shaft support of said housing.

85. (Previously Presented) The device of claim 82, wherein said at least one milling surface is configured such that it is operated in a plane generally parallel to the surface contour formed in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

86. (Previously Canceled)

87. (Previously Presented) The device of claim 82 including drive means that operatively couples said form cutter to said drive source.

88. (Previously Presented) The device of claim 87, wherein:

said drive means comprises a drive shaft having a proximal end and a distal end;

said drive shaft is adapted to be received in said elongated shaft portion;

the distal end of said drive shaft is operatively coupled to said form cutter to move said form cutter; and

the proximal end of said drive shaft is operatively coupled to said drive source.

89. (Previously Presented) The device of claim 82, wherein said drive means is disposed at least in part in said elongated shaft portion.

90. (Previously Presented) The device of claim 82, wherein:

the device includes a drive shaft disposed within said elongated shaft portion;

said drive shaft is rotatably driven by said drive source;

said drive shaft has a gear at its distal end; and

said gear is configured to mate with corresponding teeth on said form cutter.

91. (Previously Presented) The device of claim 90, wherein:

said form cutter has at least one top milling surface and a bottom surface;

said bottom surface is provided with a beveled gearing surface;

said beveled gearing surface engages teeth on said gear; and

said gear and said beveled gearing surface cooperate to rotate said form cutter as said drive shaft is rotatably driven by said drive means.

92. (Previously Presented) The device of claim 82, wherein said form cutter is driven in rotary motion by said drive means.

93. (Canceled)

94. (Previously Presented) The device of claim 93, wherein said form cutter includes a leading edge configured as a bone cutting surface.

95. (Previously Presented) The device of claim 93, wherein at least one of said at least two milling surfaces of said form is convex.

96. (Previously Presented) The device of claim 93, wherein at least one of said at least two milling surfaces of said form cutter is tapered outwardly from a front surface of said form cutter.

97. (Previously Presented) A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

98. (Previously Canceled)

99. (Canceled)

100. (Previously Presented) The device of claim 97, wherein said housing is fixedly connected to said elongated shaft portion.

101. (Previously Presented) The device of claim 97, wherein:

said housing includes a shaft support; and

said form cutter includes a form cutter shaft configured to fit within said shaft support of said housing.

102. (Previously Presented) The device of claim 97, wherein said at least one milling surface is configured such that it is operated in a plane generally parallel to the surface contour formed in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

103. (Previously Canceled)

104. (Previously Presented) The device of claim 97 including drive means that operatively couples said form cutter to said drive source.

105. (Previously Presented) The device of claim 104, wherein:

said drive means comprises a drive shaft having a proximal end and a distal end;

said drive shaft is adapted to be received in said elongated shaft portion;

the distal end of said drive shaft is operatively coupled to said form cutter to move said form cutter; and

the proximal end of said drive shaft is operatively coupled to said drive source.

106. (Previously Presented) The device of claim 97, wherein said drive means is disposed at least in part in said elongated shaft portion.

107. (Previously Presented) The device of claim 97, wherein:

the device includes a drive shaft disposed within said elongated shaft portion;

said drive shaft is rotatably driven by said drive source;

said drive shaft has a gear at its distal end; and

said gear is configured to mate with corresponding teeth on said form cutter.

108. (Previously Presented) The device of claim 107, wherein:

said form cutter has at least one top face having first and second milling surfaces and a bottom surface;

said bottom surface is provided with a beveled gearing surface;

said beveled gearing surface engages teeth on said gear; and

said gear and said beveled gearing surface cooperate to rotate said form cutter as said drive shaft is rotatably driven by said drive means.

109. (Previously Presented) The device of claim 97, wherein said form cutter is driven in rotary motion by said drive means.

110. (Canceled)

111. (Previously Presented) The device of claim 97, wherein said housing includes a surface formed on a side of said housing opposite said milling surface, said surface being configured to allow a surgeon to increase the pressure of said milling surface against the one of the adjacent vertebral bodies.

112. (Previously Canceled)

113. (Previously Canceled)

114. (Previously Presented) A form cutter for preparing a space between adjacent vertebral bodies to receive an insert, said form cutter having:

at least one milling surface and being mountable on a device capable of moving said form cutter to cause said at least one milling surface to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies;

said at least one milling surface having a profile that imparts a shape to the bone on the vertebral bodies which mates with a predetermined endoprosthesis surface shape of the insert to be received between the adjacent vertebral bodies;

said at least one milling surface having a perimeter that is at least in part arcuate; and

said form cutter having a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine.

115. (Previously Presented) The form cutter of claim 114, wherein said form cutter has a top surface and a bottom surface.

116. (Previously Presented) The form cutter of claim 115, wherein at least one of said top surface and said bottom surface comprises at least one milling surface.

117. (Previously Presented) The form cutter of claim 115, wherein at least one of said top surface and said bottom surface of said form cutter comprises at least one milling surface that is convex.

118. (Previously Presented) The form cutter of claim 115, wherein at least one of said top surface and said bottom surface of said form cutter comprises at least one milling surface that is tapered outwardly from the front surface of said form cutter.

119. (Previously Presented) The form cutter of claim 114, said at least one milling surface being configured and oriented such that it is generally parallel to the surface having a predetermined contour created in the end plate of the at least one of the adjacent vertebral bodies when in use.

120. (Previously Presented) A device for preparing a space in a human spine across a disc space and into the end plates of adjacent vertebral bodies to receive an interbody spinal insert, comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means;

a form cutter mountable on said housing and movable by said drive means;

drive means that operatively couples said form cutter to said drive source to move said form cutter;

said form cutter having a milling surface selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies as said form cutter is moved by said drive means in a plane generally parallel to the predetermined surface contour to be formed in said vertebral body;

said form cutter being driven in rotary motion by said drive means; and

said milling surface being configured to have a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of said interbody spinal insert.

121. (Previously Presented) A form cutter for preparing a space between adjacent vertebral bodies to receive an insert, said form cutter having:

at least one top milling surface for removing bone;

a bottom surface opposite said at least one top milling surface adapted to mount on a device capable of moving said form cutter;

said at least one top milling surface of said moving form cutter being capable of removing bone from an end plate of at least one of said adjacent vertebral bodies to create at least one surface in said end plate having a predetermined contour;

said at least one top milling surface having a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of said insert to be received between said adjacent vertebral bodies; and

said form cutter having a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine.

122. (Previously Presented) The form cutter of claim 121, wherein said top surface of said form cutter is capable of milling bone.

123. (Previously Presented) The form cutter of claim 121, wherein at least one milling surface provided on said top surface of said form cutter is convex.

124. (Previously Presented) The form cutter of claim 121, wherein at least one milling surface provided on said top surface of said form cutter is tapered outwardly from the front surface of said form cutter.

125. (Previously Presented) The form cutter of claim 121, wherein said at least one milling surface is configured and oriented such that it is generally parallel to the surface formed in said end plate of said vertebral body when in use.

126. (Previously Presented) A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has at least one milling surface selected to create a concaval-convex surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means, said form cutter having a beveled gearing surface on the undersurface of the form cutter,

wherein said beveled gearing surface cooperates with a pinion gear provided on the distal end of a drive shaft.

127. (Previously Presented) A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive shaft;

a drive source operably connected to said drive shaft; and

a form cutter mountable on said housing and movable by said drive shaft, wherein: said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive shaft, and an undersurface having a beveled gearing surface which cooperates with a pinion gear on said drive shaft.

128. (Previously Presented) A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein: said form cutter has at least one milling surface selected to create a concaval-convex surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

129. (Previously Presented) A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive shaft;

a drive source operably connected to said drive shaft; and

a form cutter mountable on said housing and movable by said drive shaft, wherein: said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive shaft, and an undersurface having a tooth surface which cooperates with a pinion gear on said drive shaft.

130. (Previously Presented) A device for preparing the bone of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis comprising:

a single form cutter having a profile capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined endoprosthesis surface shape;

drive means for providing a driving force to the form cutter, and

means for housing the form cutter and the drive means,

wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies and the head can perform milling action in a direction angled away from the direction of head entry into a space between opposed bodies

131. (Previously Presented) A device for preparing the bone of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis comprising:

a form cutter having a convex shape so as to prepare the bone of vertebral bodies to accept the concaval-convex shape of an endoprosthesis;

drive means for providing a driving force to the form cutter, and

means for housing the form cutter and the drive means,

wherein the form cutter has a profile having a height such that it is capable of being admitted into the space between two opposing vertebral bodies, and a head that can perform milling action in a direction angled away from the direction of head entry into a space between opposed bodies.

132. (Previously Presented) A device for preparing a space in a human spine to receive an endoprosthesis device between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has a profile selected to impart a shape in the bone of the vertebral bodies that mates with the endoprosthesis device as said form cutter is moved by said drive means.

133. (Previously Presented) A device for preparing a space in a human spine to receive an endoprosthesis device between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means; and

means for preparing a space in a human spine to receive the endoprosthesis device between adjacent vertebral bodies, said space comprising a surface contour in at least one of the adjacent vertebral bodies.

134. (Previously Presented) A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has at least one vertebral body surface contour milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.

135. (Previously Presented) A device for preparing the bone of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis comprising:

a form cutter having a profile capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined endoprosthesis surface shape;

drive means for providing a driving force to the form cutter, and

means for housing the form cutter and the drive means,

wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies and the head can perform milling action in a direction angled away from the direction of head entry into a space between opposed bodies and

rotate about a shaft extending perpendicularly from its undersurface and the space between said opposing vertebral bodies.

136. (Previously Presented) A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein: said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means, said milling surface positioned to mill in a direction perpendicular to said elongated shaft portion.

137. (Previously Presented) A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein: said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means, said surface contour being generally parallel to said elongated shaft portion.

138. (Previously Presented) A device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein: said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means, said at least one milling surface being entirely within an area formed by the adjacent vertebral bodies during milling.

**APPENDIX B - Functional Language Emphasized**

1. A drill head ***for preparing the bone of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis comprising***:

a form cutter having a profile ***capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined endoprosthesis surface shape***;

drive means for providing a driving force to the form cutter, and

means for housing the form cutter and the drive means,

***wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies.***

15. A drill head ***for preparing the bone of two opposing vertebral bodies to accept the concaval-convex shape of an endoprosthesis*** comprising:

a form cutter having a support shaft capable of imparting a concave shape to the bone of vertebral bodies;

drive means for providing a driving force to the form cutter, the drive means including a drive shaft; and

means for housing the form cutter and the drive means,

***wherein the angle between the support shaft of the form cutter and the drive shaft is approximately 96°.***

18. A milling apparatus ***for preparing surfaces of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis*** comprising:

a rotary form cutter having a profile matching the predetermined shape of the endoprosthesis, the rotary form cutter rotatable about a rotation axis;

a drive having proximal and distal ends, the drive operatively coupled to the rotary form

cutter at the distal end to provide a force for rotating the rotary form cutter; and

an elongate housing containing the rotary form cutter and the drive, the elongate housing having a longitudinal axis in the elongate direction;

wherein the rotary form cutter cuts an imparted shape into the surfaces of the vertebral bodies that matches the predetermined shape of the endoprosthesis by rotation of the rotary form cutter.

25. A device ***for preparing a space in a human spine to receive an insert between adjacent vertebral bodies***, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has at least one milling surface ***selected to create a surface contour in one of the adjacent vertebral bodies*** as said form cutter is moved by said drive means.

41. A form cutter ***for preparing a space between adjacent vertebral bodies to receive an insert***, said form cutter having:

***at least one milling surface*** and being mountable on a device ***capable of moving said form cutter to cause said at least one milling surface to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies***,

said at least one milling surface having a profile that imparts a shape ***to the bone of the vertebral bodies*** which mates with a predetermined endoprosthesis shape of the insert to be received between the adjacent vertebral bodies.

47. A device ***for preparing a space in a human spine across a disc space and into the end plates of adjacent vertebral bodies to receive an interbody spinal insert***, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source for powering said drive means;

a form cutter mountable on said housing; and

a coupling means for connecting and imparting motion from said drive means to said form cutter,

wherein:

said form cutter has ***at least one milling surface selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies*** as said form cutter is moved by said drive means; and

said milling surface is configured to have a profile that ***imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of the interbody spinal insert.***

49. A device for preparing a space ***to receive an interbody insert within and between the adjacent surfaces of vertebral bodies disposed adjacent a disc space,*** said device comprising:

an elongated shaft containing at least a portion of a drive means;

a housing positioned at the distal end of said elongated shaft portion; and

a form cutter disposed on said housing and operably connected to said drive means to be driven thereby,

wherein:

said form cutter has a milling surface;

said milling surface has a profile ***that imparts a shape to the bone of the vertebral bodies which mates with the predetermined endoprosthesis surface shape of the insert to be implanted;***

said milling surface has a configuration ***adapted to remove bone from the vertebral bodies to prepare the vertebral bodies to receive the insert***; and

said milling surface of said form ***cutter is configured to be generally parallel to a receiving surface that is formed on one of the vertebral bodies by said device.***

67. A device ***for preparing a space in the human spine to receive an insert between adjacent vertebral bodies***, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means;

a form cutter mountable on said housing and movable by said drive means;

said form cutter having at least one milling surface ***selected to create a predetermined surface contour in one of the adjacent vertebral bodies*** as said form cutter is moved by said drive means;

said drive means including a drive shaft disposed within said elongated shaft portion;

said drive shaft being rotatably driven by said drive means; and

said drive shaft being operably coupled to said form cutter.

82. A device ***for preparing a space in a human spine to receive an insert between adjacent vertebral bodies***, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means;

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has at least one milling surface ***selected to create a predetermined surface contour in one of the adjacent vertebral bodies*** as said form cutter is moved by said drive means ; and

said housing has a surface formed on a side of said housing opposite said milling surface.

97. A device ***for preparing a space in a human spine to receive an insert between adjacent vertebral bodies***, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has at least one milling surface ***selected to create a predetermined surface contour in one of the adjacent vertebral bodies*** as said form cutter is moved by said drive means.

114. A form cutter ***for preparing a space between adjacent vertebral bodies to receive an insert***, said form cutter having:

at least one milling surface and being mountable on a device capable of moving said form cutter to cause said at least one milling surface to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies;

said at least one milling surface having a profile that ***imparts a shape to the bone on the vertebral bodies which mates with a predetermined endoprosthesis surface shape of the insert to be received between the adjacent vertebral bodies***;

said at least one milling surface having a perimeter that is at least in part arcuate; and

said form cutter having a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine.

120. A device ***for preparing a space in a human spine across a disc space and into the end plates of adjacent vertebral bodies to receive an interbody spinal insert***, comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means;

a form cutter mountable on said housing and movable by said drive means;

drive means that operatively couples said form cutter to said drive source to move said form cutter;

said form cutter having a milling surface ***selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies***

***as said form cutter is moved by said drive means in a plane generally parallel to the predetermined surface contour to be formed in said vertebral body***;

said form cutter being driven in rotary motion by said drive means; and

said milling surface being configured to have a profile ***that imparts a shape to the bone of the vertebral bodies which mates with ~~a profile~~ a predetermined endoprosthesis surface shape of said interbody spinal insert.***

121. A form ***cutter for preparing a space between adjacent vertebral bodies to receive an insert***, said form cutter having:

at least one top milling surface for removing bone;

a bottom surface opposite said at least one top milling surface adapted to mount on a device capable of moving said form cutter;

said at least one top milling surface of said moving form cutter being ***capable of removing bone from an end plate of at least one of said adjacent vertebral bodies to create at least one surface in said end plate having a predetermined contour***;

said at least one top milling surface having a profile that ***imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of said insert to be received between said adjacent vertebral bodies***; and

said form cutter ***having a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine.***

128. A ***device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies***, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein: said form cutter has at least one milling surface ***selected to create a concaval-convex surface contour in one of the adjacent vertebral bodies*** as said form cutter is moved by said drive means.

130. A ***device for preparing the bone of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis*** comprising:

a single form cutter having a profile ***capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined endoprosthesis surface shape***;

drive means for providing a driving force to the form cutter, and

means for housing the form cutter and the drive means,

wherein the profile of the form cutter is of ***a height capable of being admitted into the space between two opposing vertebral bodies and the head can perform milling action in a direction angled away from the direction of head entry into a space between opposed bodies.***

131. A device ***for preparing the bone of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis*** comprising:

a form cutter having a convex shape ***so as to prepare the bone of vertebral bodies to accept the concaval-convex shape of an endoprosthesis***;

drive means for providing a driving force to the form cutter, and

means for housing the form cutter and the drive means,

wherein the form cutter has a profile having ***a height such that it is capable of being admitted into the space between two opposing vertebral bodies***, and a ***head that can perform milling action in a direction angled away from the direction of head entry into a space between opposed bodies***.

132. A device ***for preparing a space in a human spine to receive an endoprosthesis device between adjacent vertebral bodies***, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has a profile ***selected to impart a shape in the bone of the vertebral bodies that mates with the endoprosthesis device*** as said form cutter is moved by said drive means.

133. A device ***for preparing a space in a human spine to receive an endoprosthesis device between adjacent vertebral bodies***, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means; and

means ***for preparing a space in a human spine to receive the endoprosthesis device between adjacent vertebral bodies***, said space comprising a surface contour in at least one of the adjacent vertebral bodies.

134. A device ***for preparing a space in a human spine to receive an insert between adjacent vertebral bodies***, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has at least ***one vertebral body surface contour milling surface selected to create a surface contour in one of the adjacent vertebral bodies*** as said form cutter is moved by said drive means.

135. A device ***for preparing the bone of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis*** comprising:

a form cutter having a profile ***capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined endoprosthesis surface shape***;

drive means for providing a driving force to the form cutter, and

means for housing the form cutter and the drive means,

wherein the profile of the form cutter is ***of a height capable of being admitted into the space between two opposing vertebral bodies and the head can perform milling action in a direction angled away from the direction of head entry into a space between opposed***

***bodies and rotate about a shaft extending perpendicularly from its undersurface and the space between said opposing vertebral bodies.***

136. A device ***for preparing a space in a human spine to receive an insert between adjacent vertebral bodies***, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has at least one milling surface ***selected to create a surface contour in one of the adjacent vertebral bodies*** as said form cutter is moved by said drive means, said milling surface positioned to mill ***in a direction perpendicular to said elongated shaft portion.***

137. A ***device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies***, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein:

said form cutter has at least one milling surface ***selected to create a surface contour in one of the adjacent vertebral bodies*** as said form cutter is moved by said drive means, ***said surface contour being generally parallel to said elongated shaft portion.***

138. A device ***for preparing a space in a human spine to receive an insert between adjacent vertebral bodies***, said device comprising:

an elongated shaft portion;

a housing disposed at the distal end of said elongated shaft portion;

a drive means;

a drive source operably connected to said drive means; and

a form cutter mountable on said housing and movable by said drive means, wherein: said form cutter has at least one milling surface ***selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter*** is moved by said drive means, ***said at least one milling surface being entirely within an area formed by the adjacent vertebral bodies during milling***.